Healthcare Professional’s Information Pack

UK

Version 1
CONTENT OF CD-ROM
Treatment Initiation Forms
Adverse Event Forms
Pregnancy Reporting Forms
Prescription Authorisation Form
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Healthcare Professional’s Information Pack
UK

Your pack contains the information and materials needed for prescribing and dispensing Imnovid®, including information about the Pregnancy Prevention Programme.

It is a requirement of the Pregnancy Prevention Programme that all healthcare professionals ensure that they have read and understood this pack before prescribing or dispensing Imnovid® for ANY patient.

An easy reference guide is included at the back of your pack. This summarises the information for ongoing patient safety and the main steps in the Imnovid® Pregnancy Prevention Programme process.

Imnovid® Warning

Imnovid® in combination with dexamethasone is indicated in the treatment of adult patients with relapsed and refractory multiple myeloma (MM) who have received at least two prior treatments regimens, including both lenalidomide and bortezomib, and have demonstrated disease progression on the last therapy.

Imnovid® is structurally related to thalidomide. Thalidomide is a known human teratogen that causes severe life-threatening birth defects. Imnovid® was found to be teratogenic in both rats and rabbits when administered during the period of major organogenesis.

If Imnovid® is taken during pregnancy, a teratogenic effect of pomalidomide in humans is expected. Imnovid® is therefore contraindicated in pregnancy and in women of child bearing potential unless the conditions of the Pregnancy Prevention Programme in this pack are carried out.

Version 1.0
Date of preparation of text: September 2013
Information for Healthcare Professionals
Contains a booklet for prescribing physicians and pharmacists, providing an overview of the Imnovid Pregnancy Prevention Programme and summarising the safety information you will need to communicate to your patients. This section also contains the Pharmacy Registration Form.

Information for Patients
Contains booklets for your patients to take home and read, to reinforce the safety information you will provide to them during consultations.

Treatment Initiation Forms
There are three versions of this form, depending on whether your patient is a woman of childbearing potential, woman of non-childbearing potential, or male. Complete these forms before prescribing Imnovid® to your patients.

Prescription Tools
Contains prescription authorisation forms to document that safety measures have been performed prior to prescribing Imnovid®. Also contains patient pocket information card that your patients may present to other healthcare professionals to inform them about core information regarding their Imnovid® treatment.

Adverse Events and Pregnancy Reporting Forms
Complete these forms if your patient experiences an adverse event or becomes pregnant while being treated with Imnovid®, and send the information to the Celgene Drug Safety department.

Treatment checklists and algorithms

Frequently asked questions

Important contact information
Pregnancy Prevention Programme

Information for Healthcare Professionals
Prescribing or Dispensing Imnovid®

UK

Celgene contact details:
Phone: 0808 156 3059
Fax: 0808 156 3058
Email: rmp.uk.ire@celgene.com
This booklet is intended for healthcare professionals involved in prescribing or dispensing Imnovid® and contains information about:

- **Preventing harm to unborn babies:**
  If Imnovid® is taken during pregnancy it can cause severe birth defects or death to an unborn baby.

- **Other side effects of Imnovid®:**
  Further information on the most commonly observed adverse reactions with the use of Imnovid® is found in this booklet. A full list of all side effects, further information and recommended precautions can be found in the Imnovid® Summary of Product Characteristics (SmPC), which can be found on the Celgene website: www.celgene.co.uk.

- **Imnovid® Pregnancy Prevention Programme:**
  This Programme is designed to make sure that unborn babies are not exposed to Imnovid®. It will provide you with information about how to follow the programme and explain your responsibilities.

This booklet will help you understand these problems and make sure you know what to do before prescribing and dispensing Imnovid®.

For your patients’ health and safety, please read this booklet carefully. You must ensure that your patients fully understand what you have told them about Imnovid® before starting treatment.
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1.0 Introduction

1.1 Licensed indication

Imnovid® in combination with dexamethasone is indicated in the treatment of adult patients with relapsed and refractory multiple myeloma (MM) who have received at least two prior treatment regimens, including both lenalidomide and bortezomib, and have demonstrated disease progression on the last therapy.

The recommended starting dose of Imnovid® is 4 mg once daily taken orally on Days 1 to 21 of repeated 28-day cycles (21/28 days). The recommended dose of dexamethasone is 40 mg orally once daily on Days 1, 8, 15 and 22 of each 28-day treatment cycle.

For patients >75 years of age, the starting dose of dexamethasone is 20 mg once daily on Days 1, 8, 15 and 22 of each 28-day treatment cycle. No dose adjustment is required for pomalidomide.

For full details, please refer to the Summary of Product Characteristics (SmPC), which can be found on the Celgene website: www.celgene.co.uk.

1.2 Imnovid Pregnancy Prevention Programme

It is a requirement of the Pregnancy Prevention Programme that all Healthcare Professionals ensure that they have read and understood the following Safety Advice before prescribing or dispensing Imnovid® for any patient.

Imnovid® in combination with dexamethasone is indicated in the treatment of adult patients with relapsed and refractory multiple myeloma (MM) who have received at least two prior treatments regimens, including both lenalidomide and bortezomib, and have demonstrated disease progression on the last therapy. Imnovid® is structurally related to thalidomide. Thalidomide is a known human teratogen that causes severe life threatening birth defects. Imnovid® was found to be teratogenic in both rats and rabbits when administered during the period of major organogenesis.

If Imnovid® is taken during pregnancy, a teratogenic effect of pomalidomide in humans is expected. Imnovid® is therefore contraindicated in pregnancy and in women of child bearing potential unless the conditions of the Pregnancy Protection Programme in this pack are carried out.

1.3 Summary of the Pregnancy Protection Programme

- This booklet contains the information needed for prescribing and dispensing Imnovid® including information about the Pregnancy Prevention Programme

- If Imnovid® is taken during pregnancy, a teratogenic effect in humans is expected. Imnovid® is therefore contraindicated in pregnancy and in women of childbearing potential unless the conditions of the Pregnancy Prevention Programme described in this pack are carried out.

- It is a requirement of the Pregnancy Prevention Programme that all Healthcare Professionals ensure that they have read and understood this booklet before prescribing or dispensing Imnovid® for any patient.

- All men and all women of childbearing potential should undergo counselling of the need to avoid pregnancy (checklists for counselling are provided).

- Patients should be capable of complying with the requirements of safe use of Imnovid®.

- Patients must be provided with a copy of the Patient Booklet and Patient Pocket Information Card.
1.4 Overview of the Healthcare Professional’s Information Pack

All of the Imnovid® Pregnancy Prevention Programme materials are contained within the ‘Healthcare Professional’s Information Pack’, and additional copies can be obtained by using the contact details displayed on the front of this booklet. These materials can be used for counselling patients on the risks of Imnovid® and the precautions to be taken.

You must ensure that your patients fully understand what you have told them about Imnovid® before starting treatment.

This booklet contains key information for healthcare professionals for Imnovid® and contains the following:

- Imnovid® Pregnancy Prevention Programme
  - educational information
  - therapy management advice to avoid foetal exposure to Imnovid®
  - a distribution control system

- safety advice of relevance to all patients

- process for follow-up of effectiveness of the measures described in this pack

- process for reporting adverse events in patients treated with Imnovid®.

In order to obtain Imnovid®, it is a requirement of the Pregnancy Prevention Programme that all healthcare professionals ensure that they have read and understood this pack before prescribing or dispensing Imnovid® for any patient.

- Pharmacies must register with Celgene using the Pharmacy Registration Form, to be able to order and dispense Imnovid®.

- Prescribers must complete the appropriate Treatment Initiation Form with every patient before the first prescription is issued

- Every prescription for Imnovid® must be accompanied by a Prescription Authorisation Form
  - this form must be signed by prescriber and pharmacist and a copy of the Prescription Authorisation Form must be sent to Celgene.
  - this includes instances where Imnovid® is prescribed to in-patients or if a prescription has to be dispensed in two parts due to the unavailability of sufficient stock to fulfill the prescription.

- The Pharmacy Registration Form and Prescription Authorisation Form are in subsequent sections of this pack.
All patients should be given a Patient Booklet and Patient Pocket Information Card to take home — these materials remind patients of the key educational information and risks of treatment, and can be found in the Information for Patients section of this pack.

For women of childbearing potential, prescriptions of Imnovid® should be limited to 4 weeks of treatment and continuation of treatment requires a new prescription. Ideally, pregnancy testing, issuing a prescription and dispensing should occur on the same day. Dispensing of Imnovid® should occur within a maximum of 7 days of the prescription and the date of the last negative pregnancy test must be within the 3 days prior to the date of the prescription.

For all other patients, prescriptions of Imnovid® should be limited to 12 weeks and continuation of treatment requires a new prescription.

This Healthcare Professional’s Information Pack also contains adverse event reporting forms, treatment checklists, algorithms and treatment initiation forms.

1.5 Teratogenicity: Potential or Actual Foetal Exposure to Imnovid®

Imnovid® must never be used by women who are able to become pregnant unless they follow the Imnovid® Pregnancy Prevention Programme described in this pack (Section 2.0).

Since Imnovid® may be present in the semen of male patients, all male and female patients must both follow pregnancy prevention measures.

If a female patient or female partner of a male patient suspects that she is pregnant or becomes pregnant, then:

- Imnovid® must be discontinued immediately
- The woman must have a pregnancy test
- If the pregnancy test is positive, the woman should be referred to a physician experienced in teratology for further evaluation and counselling.

Any positive pregnancy test or suspected foetal exposure to Imnovid® must be reported immediately to the Medicines and Healthcare Products Regulatory Agency (MHRA) and to the Celgene Drug Safety department. In this instance you must:

- Stop treatment immediately
- Refer the patient to a physician specialised or experienced in dealing with teratology for advice and evaluation
• Notify Celgene immediately by contacting the Celgene Drug Safety Department (Tel: 0808 238 9908). Please also complete the Pregnancy Reporting Form included in this pack. Celgene will wish to follow-up with you the progress of all pregnancies.

• Report the event to the Medicines and Healthcare products Regulatory Agency (MHRA) using the ‘Yellow Card’ Scheme. Reporting forms and information can be found at www.mhra.gov.uk/yellowcard.

1.6 Safety advice relevant to all patients

In addition to information about the Pregnancy Prevention Programme, this booklet contains important advice for healthcare professionals about how to minimise the risk of adverse events during treatment with Imnovid®.

For further information about the appropriate use and safety profile of Imnovid®, please refer to the SmPC, which can be found on the Celgene website: www.celgene.co.uk.
2.0 Therapeutic management advice to avoid foetal exposure

Patients must be counselled on the risks and benefits of Imnovid® therapy, including the risk of birth defects, other side effects and important precautions associated with Imnovid® therapy.

It is not known if pomalidomide is excreted in human milk. Pomalidomide was detected in milk of lactating rats following administration to the mother. Because of the potential for adverse reactions in nursing infants from pomalidomide, a decision should be made whether to discontinue nursing or to discontinue the medicinal product, taking into account the importance of the medicinal product to the mother.

In order to provide appropriate information to your female patients about the precautions they must follow when using Imnovid®, it is important to determine whether your patient is or is not of childbearing potential.

There is no relevant use of Imnovid® in children aged 0-17 years in the indication of multiple myeloma. If you decide to treat a child or adolescent with Imnovid® then all of the conditions of the Pregnancy Prevention Programme apply. Based on the age of the patient you must carefully consider how to proceed with education and counselling regarding pregnancy prevention measures, and evaluate when to involve the patient’s parent or guardian.

2.1 Women of non-childbearing potential

Women in the following groups are considered not to have childbearing potential and do not need to undergo pregnancy testing or receive contraceptive advice.

The following are considered to not have childbearing potential.

- Age ≥ 50 years and naturally amenorrhoic for ≥ 1 year*
- Premature ovarian failure confirmed by a specialist gynaecologist
- Previous bilateral salpingo-oophorectomy, or hysterectomy
- XY genotype, Turner syndrome, uterine agenesis.

*Amenorrhoea following cancer therapy or during lactation does not rule out childbearing potential.

You are advised to refer your patient for a gynaecological opinion if you are unsure whether or not she meets these criteria.

Women of childbearing potential are all other women who are menstruating or perimenopausal, even those who abstain from sexual intercourse.

If a patient does not meet at least one of above criteria, but the treating physician considers the patient to be of non-childbearing potential, then prior approval of any deviation from these stipulated criteria should be sought from the
Celgene Medical Director. This is a mandatory requirement. If there is a need for a deviation, then you should contact Celgene Risk Management (Tel: 0808 156 3050 Email: rmp.uk.ire@celgene.com). The following information is required to assess whether a patient, who does not meet at least one of the above criteria, can be treated as a women of non-childbearing potential:

- DOB and Initials of the Patient
- Details of why the physician considers the patient to be of non-childbearing potential
- Background to why a deviation has been requested.

2.2 Women of childbearing potential

In view of the expected teratogenic risk of Imnovid®, foetal exposure should be avoided. Therefore women of childbearing potential must understand the need to avoid pregnancy, and these patients must be adequately counselled regarding the use of pregnancy prevention measures every time a prescription is issued.

Women of childbearing potential (even if they have amenorrhoea) must use one effective method of pregnancy prevention at least 4 weeks before therapy, during therapy and even in the case of dose interruptions, and for at least a further 4 weeks after stopping Imnovid® therapy. This must be followed unless the patient commits to absolute and continuous abstinence confirmed to her physician on a monthly basis.

If your patient is not established on an effective method of pregnancy prevention, she must be referred preferably to an appropriately trained health care professional for contraceptive advice in order that a pregnancy prevention method can be initiated.

The following are effective methods of pregnancy prevention

- Implant
- Levonorgestrel-releasing intrauterine system (IUS)
- Medroxyprogesterone acetate depot
- Tubal sterilisation
- Sexual intercourse with a vasectomised male partner only; vasectomy must be confirmed by two negative semen analyses
- Ovulation inhibitory progesterone-only pills (i.e., desogestrel).

Because of the increased risk of venous thromboembolism in patients with multiple myeloma taking pomalidomide and dexamethasone, combined oral contraceptive pills are not recommended. If a patient is currently using combined oral contraception the patient should switch to one of the effective methods listed above. The risk of venous thromboembolism continues for 4–6 weeks after discontinuing combined oral contraception. The efficacy of contraceptive steroids may be reduced during cotreatment with dexamethasone. Implants and levonorgestrel-releasing intrauterine systems are associated with an increased risk of infection at the time of insertion and irregular vaginal bleeding. Prophylactic antibiotics should be considered particularly in patients with severe neutropenia. Insertion of copper-releasing intrauterine devices is not recommended due to the potential risks of infection at the time of insertion and menstrual blood loss which may compromise patients with severe neutropenia or severe thrombocytopenia.

Your patient should be advised that if a pregnancy does occur whilst she is receiving Imnovid®, she must stop treatment immediately and inform her physician immediately.
If your patient needs to change or stop her pregnancy prevention method during her Imnovid® therapy, she must understand the need to discuss this first with:

- The physician prescribing her pregnancy prevention method
- The physician prescribing her Imnovid®.

If a woman of childbearing potential has sexual contact without using a pregnancy prevention method while taking Imnovid®, or believes for any reason that she may be pregnant, she must stop treatment and consult her doctor immediately.

Pregnancy testing

For women of childbearing potential a pregnancy test must be performed prior to issuing a prescription. This may be embarrassing for some patients and may need to be handled sensitively. A pregnancy test is required even if the patient has not had heterosexual intercourse since her last pregnancy test.

Women of childbearing potential must have a medically supervised pregnancy test (negative pregnancy test with a minimum sensitivity of 25 mIU/ml) prior to issuing a prescription, once established on contraception for 4 weeks, at 4 weekly intervals during therapy (including dose interruptions) and 4 weeks after the end of therapy (unless tubal sterilisation has been confirmed). This includes those women of childbearing potential who confirm absolute and continued abstinence.

Patients who are being prescribed the appropriate contraceptive method by their physician, should inform their physician about Imnovid® treatment. Patients should be advised to inform you if a change or stop of method of contraception is needed.

A pregnancy test must be performed immediately if a patient misses her period, if there is any abnormality in menstrual bleeding, if she has heterosexual intercourse without using a pregnancy prevention method, or if she suspects she is pregnant.

If a female patient has a positive pregnancy test, then:

- Stop treatment immediately
- Refer the patient to a physician specialised or experienced in dealing with teratology for advice and evaluation
- Notify Celgene immediately by contacting the Celgene Drug Safety Department (Tel: 0808 238 9908). Please also complete the Pregnancy Reporting Form included in this pack. Celgene will wish to follow-up with you the outcome of all pregnancies.

- Report the outcome to the Medicines and Healthcare products Regulatory Agency (MHRA) using the ‘Yellow Card’ Scheme. Reporting forms and information can be found at www.mhra.gov.uk/yellowcard.
2.3 Men

In view of the expected teratogenic risk of Imnovid®, foetal exposure should be avoided. Therefore your male patients must be counselled on the risks and benefits of Imnovid® therapy including the risk of birth defects, other side effects and important precautions associated with Imnovid® therapy. Inform your patient which are the effective contraceptive methods that his female partner can use.

Patients must be informed not to donate semen or sperm during or within 1 week after stopping treatment.

Pregnancy prevention

As Imnovid® is found in semen, male patients must use condoms during treatment and for 1 week after dose interruption and/or cessation of treatment if their partner is pregnant or is of childbearing potential and not using an effective pregnancy prevention method.

As a precaution, and taking into account special populations with potentially prolonged elimination time such as renal impairment, all male patients taking pomalidomide, including those who have had a vasectomy as seminal fluid may still contain pomalidomide in the absence of spermatozoa, should use condoms throughout treatment duration, during dose interruption and for 7 days after cessation of treatment if their partner is pregnant or of child bearing potential and has no contraception. Male patients should not donate semen or sperm during treatment (including during dose interruptions) and for 7 days following discontinuation of pomalidomide.

Patients should be instructed that if their partner becomes pregnant whilst he is taking Imnovid® or 7 days after he has stopped taking Imnovid® he should inform his treating physician immediately. The partner should inform their physician immediately. It is recommended that she be referred to a physician specialised in teratology for evaluation and advice.

Notify Celgene immediately by contacting the Celgene Drug Safety Department (Tel: 0808 238 9908). Please also complete the Pregnancy Reporting Form included in this pack. Celgene will wish to follow-up with you the outcome of all pregnancies.

Report the event to the Medicines and Healthcare products Regulatory Agency (MHRA) using the ‘Yellow Card’ Scheme. Reporting forms and information can be found at www.mhra.gov.uk/yellowcard.
2.4 Advice for all Patients

Your patient must be informed not to donate blood during or within one week after stopping treatment. If they discontinue therapy, they must return any unused Imnovid® to the pharmacy.

They must also understand that their Imnovid® is only for them, and it:

- Must not be shared with anyone else, even if they have similar symptoms
- Must be stored away safely so no one else could take the capsules by accident
- Must be kept out of reach and sight of children.
3.0 Healthcare Professional Obligations

Healthcare professionals have specific obligations that must be followed when prescribing or dispensing Imnovid®, which are:

**Prescriber: You must ensure that**

- Your patient is fully educated on the risks of Imnovid®
- You complete the appropriate ‘Treatment Initiation Form’ with your patient before the first prescription is issued
- You provide the patient with a ‘Patient Pocket Information Card and Patient Booklet’
- If relevant, your patient is using the appropriate pregnancy prevention measures
- Female patients of childbearing potential receive a pregnancy test, which must be negative, before every prescription that you issue
- You complete a ‘Prescription Authorisation Form’ with every prescription
  - this includes instances where Imnovid® is prescribed to in-patients or if a prescription has to be dispensed in two parts due to the unavailability of sufficient stock to fulfill the prescription.
- You prescribe Imnovid® in accordance with the measures described in this booklet and the SmPC, which can be found on the Celgene website: www.celgene.co.uk.

**Pharmacist: You must ensure that**

- Your Pharmacy is registered with the Imnovid® Pregnancy Prevention Programme. Registration will be valid for 2 years.
- Imnovid® is only dispensed if the prescription is accompanied by a Prescription Authorisation Form
  - this includes instances where Imnovid® is prescribed to in-patients or if a prescription has to be dispensed in two parts due to the unavailability of sufficient stock to fulfill the prescription.
- You check and validate the ‘Prescription Authorisation Form’ prior to dispensing Imnovid®
- You dispense Imnovid® in accordance with the measures described in this booklet
- You send a copy of the Prescription Authorisation Form to Celgene.
- You remind patients of key education messages each time Imnovid® is dispensed.
3.1 Information for Prescribers

3.1.1 Patient and healthcare professional education

As the prescribing physician, you play a central role in ensuring that Imnovid® is used safely and correctly.

Most importantly, you will be helping to ensure that your patients understand the risks involved in taking Imnovid® and that they are aware of their responsibilities in preventing foetal exposure to the drug. In addition, you may need to help your patients understand the processes involved in the Imnovid® Pregnancy Prevention Programme. This will help to prevent any delays in your patients receiving their treatment.

If you refer your patient to a fertility expert (e.g. obstetrician or gynaecologist) for further pregnancy prevention advice or pregnancy testing counselling, it is your responsibility to ensure that the fertility expert is aware of the Imnovid® Pregnancy Prevention Programme.

3.1.2 Patient counselling and education

Because of the different levels of risk, you will need to communicate different things to men, women and children. You must ensure that your patient understands the information before they complete their section of the Treatment Initiation Form.

Please make use of the Patient Booklet and Patient Pocket Information Card to help explain the relevant information. Copies of the booklet are contained in your ‘Healthcare Professional’s Information Pack’, and your patient may wish to take these materials home to read in their own time or with a relative. Further copies can be obtained by using the contact details displayed on the front of this booklet.
3.1.3 Prescribing Imnovid®

3.1.3.1 Maximum prescription lengths

- For women of childbearing potential, prescriptions of Imnovid® should be limited to 4 weeks of treatment and continuation of treatment requires a new prescription. Ideally, pregnancy testing, issuing a prescription and dispensing should occur on the same day. Dispensing of Imnovid® should occur within a maximum of 7 days of the prescription.

- For all other patients, prescriptions of Imnovid® should be limited to 12 weeks and continuation of treatment requires a new prescription.

Approval from the Celgene Medical Director is a mandatory requirement prior to any deviation from these stipulated prescription lengths. If there is a need for an exception to the maximum prescription lengths, then you should contact Celgene Risk Management (Tel: 0808 156 3059 Email: rmp.uk.ire@celgene.com). The following information is required to assess whether a deviation to the maximum prescription length can be approved:

- DOB and Initials of the Patient
- Sex and childbearing potential
- Background to why a deviation has been requested.

3.1.3.2 Initial prescription

Before issuing the initial prescription, you must:

- Counsel the patient on the safe use of Imnovid® in accordance with the measures described in this booklet and the SmPC, which can be found on the Celgene website: www.celgene.co.uk.

- Obtain their written confirmation (using the correct Treatment Initiation Form) that they have received and understood this information, and provide the patient with a copy

- Provide the patient with a Patient Booklet and Patient Pocket Information Card

- A ‘Prescription Authorisation Form’ must be provided to the patient with each Imnovid® prescription, and this will contain:
  - Patient name, date of birth and diagnosis
  - Prescriber name, signature and date
  - Patient category (women of childbearing potential, women of non-childbearing potential, or male)
3.1.3.3 Repeat of subsequent prescriptions

The patient must return to the initial prescriber for every repeat prescription of Imnovid®. If a patient is transferred or consulted by another prescriber, the initial prescriber must remind them to contact Celgene and obtain an Imnovid® ‘Healthcare Professional’s Information Pack’.

3.2 Information for Pharmacists

As a pharmacist you play an important role in ensuring that Imnovid® is used safely and correctly. Imnovid® will only be supplied to pharmacies, that have completed an ‘Imnovid® Pregnancy Prevention Programme, Pharmacy Registration Form’ and returned this form to Celgene.

3.2.1 Dispensing Imnovid®

Along with each Imnovid® prescription, prescribers must complete a Prescription Authorisation Form and instruct the patient to provide this to their pharmacy. You must only dispense Imnovid® if the prescriber has annotated this form correctly, and it must contain:

- Confirmation that they have received counselling on the safe use of Imnovid®
- For women of childbearing potential, the pregnancy test date and result.

The patient must present their ‘Prescription Authorisation Form’ to the pharmacy along with their prescription, and the pharmacy will check this form prior to dispensing Imnovid®.

Once the Prescription Authorisation Form has been checked for completeness, a copy of the Prescription Authorisation Form must be sent to Celgene.

If any information is missing, contact the doctor for verification prior to dispense. For women of childbearing potential, ideally pregnancy testing, issuing a prescription and dispensing should occur on the same day. Dispensing of Imnovid® should occur within a maximum of 7 days of the prescription date and the date of the last negative pregnancy test must be within the 3 days prior to the date of the prescription.
Please send a copy of the completed Prescription Authorisation Form to Celgene. The original copy should be kept by the pharmacist for a minimum of 2 years.

This is an absolute requirement so that Celgene can fulfill regulatory obligations to monitor PPP adherence and off-label usage.

- Every prescription for Imnovid® must be accompanied by a Prescription Authorisation Form
  - this form must be signed by prescriber and pharmacist and retained for a minimum of 2 years
  - this includes instances where Imnovid® is prescribed to in-patients or if a prescription has to be dispensed in two parts due to the unavailability of sufficient stock to fulfill the prescription.

**Prescription Authorisation Forms can be sent by fax, post (a photocopy of the form) or e-mail to Celgene, using the following contact details:**

Celgene Limited
1 Longwalk Road
Stockley Park
Uxbridge
UB11 1DB

Tel: 0808 156 3057
Fax: 0808 100 9910
Email: paf.uk.ire@celgene.com

### 3.2.2 Dispensing Advice

- Please ensure that you dispense Imnovid® blisters intact; capsules must not be removed from blisters and packaged into bottles
- For each prescription, dispense a maximum of a four-week supply for women of childbearing potential or a twelve week supply for all other patients
- Please educate all pharmacists within your pharmacy about the dispensing procedures for Imnovid®
- Instruct patients to return any unused Imnovid® to the pharmacy. Pharmacies must accept any unused Imnovid® returned by patients for destruction, and follow Good Pharmacy Practice guidelines for destruction of dangerous medicines.
4.0 Follow-up assessment of the effectiveness of the programme

The terms of the Imnovid® Marketing Authorisation require Celgene to assess the effectiveness of the Pregnancy Prevention Programme in order to ensure that all reasonable steps are being taken to reduce the risk of pregnancy in patients treated with Imnovid®.

Celgene have agreed with the MHRA that pharmacies can fulfill their obligations in this respect, by submitting all completed Prescription Authorisation Forms to Celgene. This information will be provided, in an anonymised and aggregated format, to the MHRA and the European Medicines Agency (EMA).

Celgene is obliged to provide the anonymised reports on the data received from the Prescription Authorisation Forms to the regulatory agencies. The reports are used to assess the effectiveness of risk minimisation activities and Celgene will not be able to comply if pharmacies do not provide ALL their Prescription Authorisation Forms to Celgene.
5.0 Safety Advice relevant to all parties

The following section contains advice to Healthcare Professionals about how to minimize the main risks associated with the use of Innovid®. Please refer also to SmPC (section 4.2 Posology and method of administration, 4.3 Contraindications, 4.4 Special warnings and precautions for use and 4.8 Undesirable effects).

In general, most adverse reactions occurred more frequently during the first 2 to 3 months of treatment.
Please note that the posology, adverse event profile and recommendations outlined herein, particularly in respect of neutropenia and thrombocytopenia, relate to the use of Innovid® within its licensed indication. There is currently insufficient evidence regarding safety and efficacy in any other indication.

Management of Neutropenia and Thrombocytopenia

Neutropenia and thrombocytopenia are the major dose-limiting toxicity of treatment with Innovid®.

It is therefore encouraged to monitor complete blood counts - including white blood cell count with differential, platelet count, haemoglobin and haematocrit - weekly for the first 8 weeks and monthly thereafter.

A dose modification or interruption may be required. Patients may require use of blood product support and/or growth factors.

Both neutropenia and thrombocytopenia can be managed with dose modifications and/or interruptions. Recommended dose modifications during treatment and restart of treatment with Innovid are outlined in the table below:

Dose modification or interruption instructions

<table>
<thead>
<tr>
<th>Toxicity</th>
<th>Dose Modification</th>
</tr>
</thead>
<tbody>
<tr>
<td>Neutropenia</td>
<td></td>
</tr>
<tr>
<td>• ANC &lt; 0.5 x 10^9/l or Febrile neutropenia (fever ≥38.5°C and ANC &lt; 1 x 10^9/l)</td>
<td>Interrupt pomalidomide treatment, follow CBC weekly.</td>
</tr>
<tr>
<td>• ANC return to ≥1 x 10^9/L</td>
<td>Resume pomalidomide treatment at 3 mg daily.</td>
</tr>
<tr>
<td>Thrombocytopenia</td>
<td>ANC return to ≥1 x 10⁹/l</td>
</tr>
<tr>
<td>------------------</td>
<td>--------------------------</td>
</tr>
<tr>
<td>Platelet Count &lt; 25 x 10⁹/l</td>
<td>Interrupt Imnovid® treatment, follow CBC weekly</td>
</tr>
<tr>
<td>Platelet Count return to ≥50 x 10⁹/l</td>
<td></td>
</tr>
<tr>
<td>For each subsequent drop &lt; 25 x 10⁹/l</td>
<td>Interrupt Imnovid® treatment</td>
</tr>
<tr>
<td>Platelet count return to ≥50 x 10⁹/l</td>
<td></td>
</tr>
</tbody>
</table>

ANC – Absolute Neutrophil Count; CBC – Complete Blood Count

To initiate a new cycle of Imnovid®, the neutrophil count must be ≥ 1 x 10⁹/l, the platelet count must be ≥ 50 x 10⁹/l.

In case of neutropenia, the physician should consider the use of growth factors.

For other Grade 3 or 4 adverse reactions judged to be related to Imnovid®, stop treatment and restart treatment at 1 mg less than the previous dose when an adverse reaction has resolved to ≤ Grade 2 at the physician’s discretion. If adverse reactions occur after dose reductions to 1 mg, then the medicinal product should be discontinued.

Neutropenia occurred in 45.3% of patients who received Imnovid® plus low dose dexamethasone (POM + LD-Dex), and in 19.5% of patients who received high dose dexamethasone (HD-Dex). Neutropenia was Grade 3 or 4 in 41.7% of patients who received POM + LD-Dex, compared with 14.8% who received HD-Dex.

In POM + LD-Dex treated patients neutropenia was infrequently serious (2.0% of patients), did not lead to treatment discontinuation, and was associated with treatment interruption in 21.0% of patients, and with dose reduction in 7.7% of patients.

Febrile neutropenia (FN) was experienced in 6.7% of patients who received POM + LD-Dex, and in no patients who received HD-Dex. All were reported to be Grade 3 or 4. FN was reported to be serious in 4.0% of patients. FN was associated with dose interruption in 3.7% of patients, and with dose reduction in 1.3% of patients, and with no treatment discontinuations.

Thrombocytopenia occurred in 27.0% of patients who received POM + LD-Dex, and 26.8% of patients who received HD-Dex. Thrombocytopenia was Grade 3 or 4 in 20.7% of patients who received POM + LD-Dex and in 24.2% who received HD-Dex. In POM + LD-Dex treated patients, thrombocytopenia was infrequently serious in 1.7% of patients, led to dose reduction in 6.3% of patients, to dose interruption in 8% of patients and to treatment discontinuation in 0.7% of patients. (see sections 4.2 and 4.4 of SmPC)
5.1 Management of Thromboembolic Events

In clinical studies, patients received prophylactic acetylsalicylic acid or alternative anti-thrombotic therapy.

Anti-coagulation therapy unless contraindicated is recommended, (such as acetylsalicylic acid, warfarin, heparin or clopidogrel), especially in patients with additional thrombotic risk factors.

Action should be taken to try to minimize all modifiable risk factors for thromboembolic events (e.g. smoking cessation, control of hypertension and hyperlipidaemia). Patients with known risk factors for thromboembolism including previous history of thrombosis should be closely monitored.

Physicians are advised to be observant for the signs and symptoms of thromboembolism. Patients should be instructed to seek medical care if they develop symptoms such as shortness of breath, chest pain, arm or leg swelling.

The use of erythropoietic agents carries a risk of thrombotic events including thromboembolism. Therefore, erythropoietic agents, as well as other agents that may increase the risk of thromboembolic events, should be used with caution.

Because of the increased risk of venous thromboembolism in patients with multiple myeloma, combined oral contraceptive pills are not recommended. If a patient is currently using combined oral contraception the patient should switch to another effective method; refer to the SmPC and the separate Healthcare Professional Booklet on the PPP for further information. The risk of venous thromboembolism continues for 4–6 weeks after discontinuing combined oral contraception.

If the patient experiences any thromboembolic events, treatment should be discontinued and standard anticoagulation therapy started. Once the patient has been stabilised on the anticoagulation treatment and any complications of the thromboembolic event have been managed, the Innovid® treatment may be restarted at the original dose dependent upon a benefit risk assessment. The patient should continue anticoagulation therapy during the course of Innovid® treatment.

Venous embolic or thrombotic events (VTE) occurred in 3.3% of patients who received POM + LD-Dex, and in 2.0% of patients who received HD-Dex. Grade 3 or 4 reactions occurred in 1.3 % of patients who received POM + LD-Dex, and no patients who received HD-Dex. In POM + LD-Dex treated patients, VTE was reported as serious in 1.7% of patients, no fatal reactions were reported in clinical studies, and VTE was not associated with dose discontinuation.
5.2 Infection

Imnovid® may cause neutropenia, which can make the patient more prone to infections. Infection was the most common non haematological toxicity; Most of those infections were Grade 3-4 Pneumonia and upper respiratory tract infections were the most commonly reported.

Prophylactic antibiotic therapy (unless contraindicated) should be considered. A decision to take prophylactic measures should be made after a careful assessment of the individual patient's underlying risk factors.

5.3 Peripheral Neuropathy

Patients with ongoing ≥Grade 2 peripheral neuropathy were excluded from clinical studies with Imnovid®. Appropriate caution should be exercised when considering the treatment of such patients with Imnovid®.

5.4 Tumour Lysis Syndrome

Tumour lysis syndrome may occur. The patients at greatest risk of tumour lysis syndrome are those with high tumour burden prior to treatment. These patients should be monitored closely and appropriate precautions taken.

5.5 Dizziness and confusion

Dizziness and confusional state have been reported with Imnovid®. Patients must avoid situations where dizziness or confusion may be a problem and not to take other medicinal products that may cause dizziness or confusion without first seeking medical advice. Patients can reduce impact by taking Imnovid® at night.

5.6 Renal impairment

A study in subjects with renal impairment has not been conducted with Imnovid®. Patients with moderate or severe renal impairment (creatinine clearance <45 mL/min) were excluded from clinical studies. Patients with renal impairment should be carefully monitored for adverse reactions.

5.7 Hepatic impairment

A study in subjects with hepatic impairment has not been conducted with Imnovid®. Patients with serum total bilirubin > 2.0 mg/dL were excluded from clinical studies. Patients with hepatic impairment should be carefully monitored for adverse reactions.

5.8 Safety and off-label use

Please note that the posology, adverse event profile and recommendations outlined above, relate to the use of Imnovid® within its licensed indication.

Imnovid® must always be used according to the Pregnancy Prevention Programme described in this pack – these precautions must be followed, irrespective of the treatment setting, including the indication for treatment.

It is essential that the patient’s diagnosis is entered on the Prescription Authorisation Form - this will allow an assessment of the clinical usage of Imnovid®, which is important for ongoing monitoring of safety.
5.9 Disposal of unwanted medicine

Patients should be advised never to give Imnovid® to another person and to return any unused capsules to their pharmacist at the end of the treatment.

5.10 Blood donation

All patients should not donate blood during treatment (including dose interruptions) and for 7 days after cessation of treatment with Imnovid®.

6.0 Reporting Adverse Events

6.1 Requirements in the event of a suspected pregnancy

- Stop treatment immediately.
- Refer patient to a physician specialised or experienced in teratology for evaluation and advice.
- Notify Celgene of all such occurrences.
- Pregnancy Reporting Form is included in this pack
- Celgene Drug Safety (Tel: 0808 238 9908, Fax: 0844 801 0468, Email: drugsafetyuk@celgene.com)
- Celgene will wish to follow-up with you the outcome of all pregnancies.
- Pregnancy reports should also be reported to the MHRA via the ‘Yellow Card’ scheme, reporting forms and information can be found at www.yellowcard.mhra.gov.uk

6.2 Reporting of Adverse Reactions

The safe use of Imnovid® is of paramount importance. As part of Celgene’s ongoing safety monitoring, the company wishes to learn of Adverse Reactions that have occurred during the use of Imnovid®. Adverse Reaction report forms are included in this Healthcare Professional Kit.

Adverse Reactions should be reported to:
Celgene Drug Safety
Tel: 0808 238 9908
Fax: 0844 801 0468
Email: drugsafetyuk@celgene.com

Adverse Reactions should also be reported to the MHRA via the ‘Yellow Card’ scheme, reporting forms and information can be found at www.yellowcard.mhra.gov.uk
Contact Details

Risk Management:
For information and questions on the risk management of Celgene’s products, the Pregnancy Prevention Programme and pharmacy registrations.
Tel: 0808 156 3059
Fax: 0808 156 3058
Email: rmp.uk.ire@celgene.com

Drug Safety:
To report any adverse events to Celgene.
Tel: 0808 238 9908
Fax: 0844 801 0468
Email: drugsafetyuk@celgene.com
Adverse events can also be reported to the MHRA using a ‘Yellow Card’ – reporting forms and information can be found at www.mhra.gov.uk/yellowcard.

Medical Information:
To obtain Medical Information on Celgene’s products.
Tel: 0844 801 0045
Fax: 0844 801 0046
Email: medinfo.uk.ire@celgene.com

Website:
Reference safety information (including the summary of product characteristics) and educational materials for all of Celgene’s products are available from our website - www.celgene.co.uk

Distributor:
For product delivery enquiries.

In Great Britain and Northern Ireland
Tel: 0208 831 8483
Fax: 0208 831 8792
Email: orders-uk@celgene.com
Imnovid® Pharmacy Registration Form – Part 1

To be completed by the Chief Pharmacist or appointed deputy.

Institution name: 

Chief Pharmacist (or appointed deputy): 

Contact telephone number: 

Email: 

Delivery Address: 

Invoice Address (if different): 

Tel: 

Fax: 

Email: 

Tel: 

Fax: 

Email: 

On behalf of .......................................................... [institution name], I agree to implement the following risk minimisation procedures when dealing with prescriptions for Imnovid as specified by Celgene in the Imnovid Healthcare Professional’s Information Pack.

1 Imnovid will be dispensed, checked and stored according to our standard documented procedures for oral anti-cancer medicines.

2 Prescriptions for Imnovid will be dispensed only if accompanied by a completed Imnovid Prescription Authorisation Form.

3 All pharmacists who dispense Imnovid will have read and understood the Imnovid Healthcare Professional’s Information Pack.

4 The pharmacist dispensing Imnovid will check each prescription and Prescription Authorisation Form for completeness and countersign the authorisation form prior to dispensing.

5 Dispensing will be limited to no more than a 4-week supply for women of childbearing potential, and 12 weeks for males and women of non child bearing potential.

6 After dispensing, Imnovid Prescription Authorisation Forms will be kept in pharmacy for a minimum of 2 years. A copy of each completed Prescription Authorisation Form will be sent to Celgene.

7 The information supplied to Celgene on Prescription Authorisation Forms will be used to provide anonymised aggregate reports to the regulatory agencies to assess implementation of the Pregnancy Prevention Programme.

8 I have read and understood the Imnovid Healthcare Professional’s Information Pack.

I understand that registration to obtain and supply Imnovid will only be granted if I agree to items 1–8 described above. Registration is valid for 2 years at which point I will confirm that we are continuing to follow the risk minimisation procedures by completing this form and sending to Celgene.

Sign: 

Print: Date: DD MM YYYY

Fax the completed forms to Celgene on 0808 156 3058
Imnovid® Pharmacy Registration Form – Part 2

If you would like to register additional pharmacy sites to be covered by your registration please provide details below.

Institution name:

Additional pharmacy sites covered by registration with Celgene to supply Imnovid®

Name of Hospital/Pharmacy:
Pharmacy purchasing contact:
Delivery Address: Invoice Address (if different):
Tel: Tel:
Fax: Fax:
Email: Email:

Name of Hospital/Pharmacy:
Pharmacy purchasing contact:
Delivery Address: Invoice Address (if different):
Tel: Tel:
Fax: Fax:
Email: Email:

Name of Hospital/Pharmacy:
Pharmacy purchasing contact:
Delivery Address: Invoice Address (if different):
Tel: Tel:
Fax: Fax:
Email: Email:

Fax the completed forms to Celgene on 0808 156 3058
Information for Patients
Contains booklets for your patients to take home and read, to reinforce the safety information you will provide to them during consultations.
Imnovid®

Pregnancy Prevention Programme

Information for Patients Taking Imnovid®

UK
Summary

- Imnovid® is the trade name for pomalidomide
- Imnovid® has been shown to produce birth defects in animals and it is expected to have a similar effect in humans
- Imnovid® is expected to be harmful to the unborn child
- Imnovid® must never be taken by a woman who is pregnant or who could become pregnant
- Men taking Imnovid® must use a condom during sexual contact with a pregnant woman or a woman who is able to become pregnant (who may not be on effective contraception) while taking Imnovid. Men should also use a condom for 1 week after stopping Imnovid treatment.
- People taking Imnovid must not donate blood while they are taking Imnovid® or for 1 week after stopping
- Imnovid® must never be shared with anyone else
- Unused Imnovid® capsules must be returned to a pharmacy for safe disposal as soon as possible

You must contact your hospital team urgently if you suspect that you or your partner is pregnant.

Like all medicines Imnovid® can cause side-effects, although not everybody gets them. Some are more common than others and some are more serious than others. If you notice any of the problems below you must contact your doctor or hospital team immediately (you will find more details on these, and other side-effects in this brochure).

You must contact your hospital team urgently if you feel unwell or develop any of the following:

- Any fever, chills, sore throat, cough, mouth ulcers or any other symptoms of infection
- Any bleeding or bruising in the absence of injury
- Any chest or leg pain
- Any shortness of breath
- Any other symptom that causes concern

Please ask your doctor or nurse if you need more information or an explanation of any of the terms used in this booklet.
Safety information for all patients
You must never take Imnovid® if:
• You are pregnant
• You are breastfeeding
• You are a woman who is able to become pregnant, even if you are not planning to become pregnant. Women able to become pregnant must use an effective form of contraception for 4 weeks before starting Imnovid®, throughout the duration of the treatment and for 4 weeks after stopping treatment
• You are allergic to Imnovid® or to any of the other ingredients contained in the capsule.

Imnovid® would be harmful to an unborn baby
• Imnovid® is structurally related to thalidomide, which is known to cause severe, life-threatening birth defects
• An unborn child would be likely to be harmed if exposed to Imnovid® during pregnancy

Women
If Imnovid® is taken during pregnancy, severe, life-threatening birth defects are expected. If you are pregnant, if you think you may be pregnant or if you are planning to become pregnant you must not take Imnovid®. Even if you are not having regular periods or are approaching the menopause you may still be able to become pregnant.

If for any reason you think you may be pregnant while you are taking Imnovid®, or in the 4 weeks after stopping, you must immediately stop taking Imnovid® and contact your doctor.

Men
Imnovid® passes into human semen. If your partner is pregnant or able to become pregnant, and she doesn’t use effective contraception, you must use condoms, during treatment, during dose interruptions and 1 week after the end of treatment even if you have had a vasectomy.

You must contact your hospital team or doctor urgently if you suspect that your partner may be pregnant while you are taking Imnovid®, or in the 4 weeks after you stop.
**Side effects**
Like all medicines, Imnovid® can cause side-effects, although not everybody gets them. Some are more common than others and some are more serious than others. These are not all the side-effects that have been reported with Imnovid®. Ask your doctor or pharmacist if you would like more information.

Almost all side-effects are temporary and can be easily prevented or treated. The most important thing is to be aware of what to expect and what to report to your doctor.

It is important that you talk to your doctor if you have any side-effects during Imnovid® treatment. You may also report any side-effect to the UK Medicines and Healthcare products Regulatory Agency via their ‘Yellow Card’ scheme, by using their web site at www.yellowcard.gov.uk.

**Women Patients of Childbearing Potential**

- Imnovid® is the trade name for pomalidomide.
- Pomalidomide is structurally related to thalidomide, which is known to cause severe life-threatening birth defects, therefore pomalidomide is expected to be harmful to the unborn child.
- Imnovid® has been shown to produce birth defects in animals and it is expected to have a similar effect in humans.
- You should never share Imnovid® with anyone else.
- You should always return any unused capsules to the pharmacist for safe disposal as soon as possible.
- You should not donate blood during treatment and for 7 days after treatment finishes, this includes dose interruptions.
- If you experience any side effects whilst taking Imnovid® you should tell your doctor.
- For additional information, please refer to the Patient Leaflet.
Blood clots and infections

Imnovid® treatment may increase the risk of you developing blood clots in some veins and arteries ("thromboembolic events") in the body. People with myeloma may already have a higher risk of blood clots. Symptoms of a blood clot can be leg pains, swelling and redness of the lower legs or arms. This may be due to blood clots in the veins of your leg (deep vein thrombosis).
Sometimes the clots can travel in your bloodstream to your lungs producing symptoms of chest pain and breathlessness.

Therefore you must tell your doctor immediately if you experience:
• any fever, chills, sore throat, cough, mouth ulcers or any other signs of infection (due to reduced number of white blood cells, which fight infection)
• any bleeding or bruising in the absence of injury
• any chest or leg pain and swelling, especially in your lower leg or calves
• any shortness of breath.

You may be prescribed treatment to help prevent blood clots from forming.
If you have any risk factors for developing thromboembolic events, e.g. smoking, high blood pressure, high cholesterol, a clotting disorder, a previous blood clot (in a vein or artery), you should tell your doctor.
Damage to nerves in the hands and feet
Imnovid® treatment may increase the risk of you developing damage to nerves in the hands and feet (“peripheral neuropathy”). Many of the treatments for myeloma can cause damage to nerves in the hands and feet, or make current symptoms worse.

Therefore you must tell your doctor immediately if you experience:
• any tingling sensation or numbness to pain
• any muscle weakness
• any spasms

Feeling confused or less alert
You should avoid situations where feeling confused or less alert may be a problem and you should first seek medical advice before taking other medicinal products known to cause feeling confused or less alert. You can reduce impact by taking pomalidomide at night.

What should you tell your doctor before taking Imnovid
• If you are pregnant, if you think you may be pregnant or if you are planning to become pregnant, as Imnovid is expected to be harmful to an unborn child
• If you think you are able to become pregnant and need advice on effective contraception
• If you are breastfeeding
• If you have previously had an allergic (hypersensitive) reaction such as rash, itching, swelling, feeling dizzy or trouble breathing while taking related medicines called ‘thalidomide’ or ‘lenalidomide.
• If you have previously had an allergic (hypersensitive) reaction such as rash, itching, swelling, feeling dizzy or trouble breathing to any other ingredient in Imnovid® capsules. Ask your pharmacist for advice
• If you have a history of kidney problems
• If you have a history of liver problems
• If you have a history of thrombosis (blood clots)
• If you are taking or have recently taken any other medicines, including medicines bought without a prescription.
How to take your medication

Your pharmacist can give you help and advice on taking your medicines. Some people find it helpful to mark on a calendar when they have taken their medicines each day or to set an alarm clock to remind them to take their medicines.

Imnovid

- Your doctor will prescribe a dose of Imnovid® suited to you
- Imnovid® is taken orally (by mouth) usually once each day for 21 days followed by a 7-day rest. The total 28 days is called a cycle.
- Your doctor may adjust your dose depending on the result of blood tests and any side-effects you may experience
- Do not take more capsules than your doctor has prescribed. If in doubt, ask your doctor or pharmacist for advice
- Imnovid® capsules should be swallowed whole, with a glass of water, with or without food

Imnovid® can be taken at any time of day but it should be taken at approximately the same time each day

Dexamethasone

- Imnovid® is licensed to be taken in combination with dexamethasone and therefore you are likely to receive both
- If you are also taking dexamethasone tablets you can take these at the same time as Imnovid®
- Dexamethasone is usually only taken for a few days each week. Follow the instructions from your doctor/pharmacist carefully

What to do if you have taken more than the prescribed dose of Imnovid®:
If you accidentally take too many capsules, contact your doctor immediately.

Taking other medicines

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines bought without a prescription. If you are seeing a different doctor or other healthcare professional for treatment (your dentist for example) you should tell them that you are taking Imnovid and dexamethasone.

How to store Imnovid® safely

- Keep your Imnovid® in a safe place out of the reach and sight of children.
- Keep your Imnovid capsules in the original box at room temperature.
- Do not use after the expiry date written on the box.

End of Treatment Requirements

After completing your Imnovid® treatment, it is important that:

- You return any unused Imnovid® capsules to your pharmacist
- You do not donate blood for 7 days.
- Continue using your effective pregnancy prevention method for a further 4 weeks
- Your doctor will perform a final pregnancy test after 4 weeks.
Pregnancy Prevention Programme

- If Imnovid® is taken during pregnancy, severe, life-threatening birth defects are expected. If you are pregnant, if you think you may be pregnant or if you are planning to become pregnant you should tell your doctor and MUST NOT take Imnovid®. Even if you are not having regular periods or are approaching the menopause you may still be able to become pregnant.
- In order to ensure that an unborn baby is not exposed to Imnovid®, your doctor will complete a Prescription Authorisation Form documenting that you have been informed of the requirement for you NOT to become pregnant during treatment with Imnovid® and for one month after finishing Imnovid®.

You should tell your doctor if you are pregnant or think you may be pregnant or are planning to become pregnant, as Imnovid® is expected to be harmful to an unborn child.

- If you are able to become pregnant, you must follow all the necessary measures to prevent you becoming pregnant and ensuring you are not pregnant during treatment. Before starting the treatment, you should ask your doctor if you are able to become pregnant, even if you think this is unlikely.
- If you are able to become pregnant and even if you agree and confirm every month that you will not engage in heterosexual activity you will have pregnancy tests under the supervision of your doctor before treatment. These will be repeated every 4 weeks during treatment, during dose interruption and 4 weeks after the treatment has finished (unless it is confirmed that you have had a tubal sterilisation)
- You should start your Imnovid® treatment as soon as possible after having a negative pregnancy test result.
- If you are able to become pregnant you must use effective methods of contraception for 4 weeks before starting treatment, during treatment (including dose interruptions), and until 4 weeks after stopping treatment.
  Your doctor will advise you on appropriate methods of contraception as some types of contraception are not recommended with Imnovid®.
  It is essential therefore that you discuss this with your doctor.
- To get advice on appropriate contraception - please ask your doctor.
- If you suspect you are pregnant at any time whilst taking Imnovid® or in the 4 weeks after stopping treatment, you must stop Imnovid® immediately and immediately inform your doctor. Your doctor will refer you to a physician specialised or experienced in teratology for evaluation and advice.
- Inform your doctor prescribing the contraception that you are on Imnovid®.
- Inform your doctor prescribing Imnovid® if you have changed or stopped the method of contraception.

Before starting Imnovid® treatment you should discuss with your doctor whether or not there is any possibility that you could become pregnant. Some women who are not having regular periods or who are approaching the menopause may still be able to become pregnant.
Unless you fall into one of the following categories you must follow the pregnancy prevention advice presented in this section:

- You are at least 50 years old and it has been at least one year since your last period (if your periods have stopped because of cancer therapy or during lactation, then there is still a chance you could become pregnant)
- Your womb has been removed (hysterectomy)
- Your fallopian tubes and both ovaries have been removed (bilateral salpingo oophorectomy)
- You have premature ovarian failure, confirmed by a specialist gynaecologist
- You have the XY genotype, Turner’s syndrome or uterine agenesis

You may need an appointment and tests with a specialist in female medicine to confirm that you cannot become pregnant. Every woman who is able to become pregnant even if they are not planning to must follow the precautions detailed in this section.

**Contraception to prevent pregnancy**

If you are a woman who could become pregnant you must either:

- Use adequate contraception starting 4 weeks before Immnovid® treatment, during Immnovid® treatment, during any breaks in Immnovid® treatment and for 4 weeks after stopping Immnovid treatment
- or
- Agree you will not engage in sexual activity with a male partner starting 4 weeks before Immnovid® treatment, during Immnovid® treatment, during any breaks in Immnovid® treatment and for 4 weeks after stopping Immnovid® treatment. You will be asked to confirm this every month.

Not all types of contraception are suitable during Immnovid treatment. You and your partner should discuss with your doctor suitable forms of contraception that you both find acceptable. If necessary, your hospital team can refer you to a specialist for advice on contraception.

**Women Patients Not of Child Bearing Potential**

- Immnovid® is the trade name for pomalidomide.
- Pomalidomide is structurally related to thalidomide, which is known to cause severe life-threatening birth defects, therefore pomalidomide is expected to be harmful to the unborn child.
- Immnovid® has been shown to produce birth defects in animals and it is expected to have a similar effect in humans.
- You should never share Immnovid® with anyone else.
- You should always return any unused capsules to the pharmacist for safe disposal as soon as possible.
- You should not donate blood during treatment and for 7 days after treatment finishes, this includes dose interruptions.
- If you experience any side effects whilst taking Immnovid® you should tell your doctor.
- For additional information, please refer to the Patient Leaflet.

**Safety Information for all Patients**

You must never take Immnovid® if:

- You are allergic to Immnovid® or to any of the other ingredients contained in the capsule.
- Pomalidomide is structurally related to thalidomide, which is known to cause severe, life-threatening birth defects
- Immnovid® is expected to be harmful to an unborn baby
Side effects
Like all medicines, Innovid® can cause side-effects, although not everybody gets them. Some are more common than others and some are more serious than others. Ask your doctor or pharmacist if you would like more information, and refer to the Package Leaflet. Almost all side-effects are temporary and can be easily prevented or treated. The most important thing is to be aware of what to expect and what to report to your doctor. It is important that you talk to your doctor if you have any side-effects during Innovid® treatment.

Blood clots and infection
Innovid® treatment may increase the risk of you developing blood clots in some veins and arteries (“thromboembolic events”) in the body. People with myeloma may already have a higher risk of blood clots. Symptoms of a blood clot can be leg pains, swelling and redness of the lower legs or arms. This may be due to blood clots in the veins of your leg (deep vein thrombosis). Sometimes the clots can travel in your bloodstream to your lungs producing symptoms of chest pain and breathlessness.

Therefore you must tell your doctor immediately if you experience:
- any fever, chills, sore throat, cough, mouth ulcers or any other signs of infection (due to reduced number of white blood cells, which fight infection)
- any bleeding or bruising in the absence of injury
- any chest or leg pain and swelling, especially in your lower leg or calves
- any shortness of breath.

You may be prescribed treatment to help prevent blood clots from forming. If you have any risk factors for developing thromboembolic events, e.g. smoking, high blood pressure, high cholesterol, a clotting disorder, a previous blood clot (in a vein or artery), you should tell your doctor.

Damage to nerves in the hands and feet
Innovid® treatment may increase the risk of you developing damage to nerves in the hands and feet (“peripheral neuropathy”). Many of the treatments for myeloma can cause damage to nerves in the hands and feet, or make current symptoms worse.

Therefore you must tell your doctor immediately if you experience:
- any tingling sensation or numbness to pain
- any muscle weakness
- any spasms

Feeling confused or less alert
You should avoid situations where feeling confused or less alert may be a problem and you should first seek medical advice before taking other medicinal products known to cause feeling confused or less alert. You can reduce impact by taking pomalidomide at night.
What should you tell your doctor before taking Imnoid®
- If you have previously had an allergic (hypersensitive) reaction such as rash, itching, swelling, feeling dizzy or trouble breathing while taking related medicines called ‘thalidomide’ or ‘lenalidomide’
- If you have previously had an allergic (hypersensitive) reaction such as rash, itching, swelling, feeling dizzy or trouble breathing to any other ingredient in Imnoid capsules. Ask your pharmacist for advice
- If you have a history of kidney problems
- If you have a history of liver problems
- If you have a history of thrombosis (blood clots)
- If you are taking or have recently taken any other medicines, including medicines bought without a prescription.

How to take your medication
Your pharmacist can give you help and advice on taking your medicines. Some people find it helpful to mark on a calendar when they have taken their medicines each day or to set an alarm clock to remind them to take their medicines.

Imnoid
- Your doctor will prescribe a dose of Imnoid suited to you
- Imnoid® is taken orally (by mouth) usually once each day for 21 days followed by a 7-day rest. The total 28 days is called a cycle
- Your doctor may adjust your dose depending on the result of blood tests and any side-effects you may experience
- Do not take more capsules than your doctor has prescribed. If in doubt, ask your doctor or pharmacist for advice
- Imnoid® capsules should be swallowed whole, with a glass of water, can be taken with or without food
- Imnoid® can be taken at any time of day but it should be taken at approximately the same time each day

Dexamethasone
- Imnoid® is licensed to be taken in combination with dexamethasone and therefore you are likely to receive both
- If you are also taking dexamethasone tablets you can take these at the same time as your Imnoid®
- Dexamethasone is usually only taken for a few days each week. Follow the instructions from your doctor/pharmacist carefully

What to do if you have taken more than the prescribed dose of Imnoid®
If you accidentally take too many capsules, contact your doctor immediately.

Taking other medicines
Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines bought without a prescription. If you are seeing a different doctor or other healthcare professional for treatment (your dentist for example) you should tell them that you are taking Imnoid® and dexamethasone.
How to store Imnovid® safely
• Keep your Imnovid® in a safe place out of the reach and sight of children.
• Keep your Imnovid® capsules in the original box at room temperature.
• Do not use after the expiry date written on the box.

End of Treatment Requirements
After completing your Imnovid® treatment, it is important that:
• You return any unused Imnovid capsules to your pharmacist
• You do not donate blood for 7 days.

Pregnancy Prevention Programme
• In order to ensure that an unborn baby is not exposed to Imnovid®, your doctor will complete a Prescription Authorisation Form documenting that you are not able to become pregnant.

You are considered to be a women who is not able to become pregnant if you fall into one of the following categories:

• You are at least 50 years old and it has been at least one year since your last period (if your periods have stopped because of cancer therapy or during lactation, then there is still a chance you could become pregnant)
• Your womb has been removed (hysterectomy)
• Your fallopian tubes and both ovaries have been removed (bi-lateral salpingo oophorectomy)
• You have premature ovarian failure, confirmed by a specialist gynaecologist
• You have the XY genotype, Turner’s syndrome or uterine agenesis.

Male patients
• Imnovid® is the trade name for pomalidomide.
• Pomalidomide is structurally related to thalidomide, which is known to cause severe life-threatening birth defects, therefore pomalidomide is expected to be harmful to the unborn child.
• Pomalidomide has been shown to produce birth defects in animals and it is expected to have a similar effect in humans.
• Ask your doctor to inform you on which are the effective contraceptive methods that your female partner can use
• You should never share Imnovid® with anyone else.
• You should always return any unused capsules to the pharmacist for safe disposal as soon as possible.
• You should not donate blood during treatment and for 7 days after treatment finishes, this includes dose interruptions.
• You should not donate semen or sperm during treatment and for 7 days after treatment finishes, this includes dose interruptions.
• If you experience any side effects whilst taking Imnovid you should tell your doctor.
• For additional information, please refer to the Patient Leaflet.
Safety Information for all Patients

- You must never take Imnovid® if:
- You are allergic to Imnovid or to any of the other ingredients contained in the capsule.
- Pomalidomide is structurally related to thalidomide, which is known to cause severe, life-threatening birth defects
- Imnovid® is expected to be harmful to an unborn baby
- Ask your doctor to inform you on which are the effective contraceptive methods that your female partner can use

Side effects
Like all medicines, Imnovid® can cause side-effects, although not everybody gets them. Some are more common than others and some are more serious than others. Ask your doctor or pharmacist if you would like more information, and refer to the Package Leaflet. Almost all side-effects are temporary and can be easily prevented or treated. The most important thing is to be aware of what to expect and what to report to your doctor. It is important that you talk to your doctor if you have any side-effects during Imnovid® treatment.

Blood clots and infections
Imnovid® treatment may increase the risk of you developing blood clots in some veins and arteries ("thromboembolic events") in the body. People with myeloma may already have a higher risk of blood clots. Symptoms of a blood clot can be leg pains, swelling and redness of the lower legs or arms. This may be due to blood clots in the veins of your leg (deep vein thrombosis). Sometimes the clots can travel in your bloodstream to your lungs producing symptoms of chest pain and breathlessness.

Therefore you must tell your doctor immediately if you experience:
- any fever, chills, sore throat, cough, mouth ulcers or any other signs of infection (due to reduced number of white blood cells, which fight infection)
- any bleeding or bruising in the absence of injury
- any chest or leg pain and swelling, especially in your lower leg or calves
- any shortness of breath.

You may be prescribed treatment to help prevent blood clots from forming. If you have any risk factors for developing thromboembolic events, e.g. smoking, high blood pressure, high cholesterol, a clotting disorder, a previous blood clot (in a vein or artery), you should tell your doctor.

Damage to nerves in the hands and feet
Imnovid® treatment may increase the risk of you developing damage to nerves in the hands and feet ("peripheral neuropathy"). Many of the treatments for myeloma can cause damage to nerves in the hands and feet, or make current symptoms worse.

Therefore you must tell your doctor immediately if you experience:
- any tingling sensation or numbness to pain
- any muscle weakness
- any spasms

Feeling confused or less alert
You should avoid situations where feeling confused or less alert may be a problem and you should first seek medical advice before taking other medicinal products known to cause feeling confused or less alert. You can reduce impact by taking pomalidomide at night
What should you tell your doctor before taking Imnovid®

- If your partner is pregnant, or if you think your partner may be pregnant or if your partner is planning to become pregnant, as Imnovid may be harmful to an unborn child
- If you have previously had an allergic (hypersensitive) reaction such as rash, itching, swelling, feeling dizzy or trouble breathing while taking related medicines called ‘thalidomide’ or ‘lenalidomide’
- If you have previously had an allergic (hypersensitive) reaction such as rash, itching, swelling, feeling dizzy or trouble breathing to any other ingredient in Imnovid® capsules.
  Ask your pharmacist for advice
- If you have a history of kidney problems
- If you have a history of liver problems
- If you have a history of thrombosis (blood clots)
- If you are taking or have recently taken any other medicines, including medicines bought without a prescription.

How to take your medication

Your pharmacist can give you help and advice on taking your medicines. Some people find it helpful to mark on a calendar when they have taken their medicines each day or to set an alarm clock to remind them to take their medicines.

Imnovid®

- Your doctor will prescribe a dose of Imnovid® suited to you
- Imnovid® is taken orally (by mouth) usually once each day for 21 days followed by a 7-day rest. The total 28 days is called a cycle
- Your doctor may adjust your dose depending on the result of blood tests and any side-effects you may experience
- Do not take more capsules than your doctor has prescribed. If in doubt, ask your doctor or pharmacist for advice
- Imnovid® capsules should be swallowed whole, with a glass of water, can be taken with or without food
- Imnovid® can be taken at any time of day but it should be taken at approximately the same time each day

Dexamethasone

- Imnovid® is licensed to be taken in combination with dexamethasone and therefore you are likely to receive both
- If you are also taking dexamethasone tablets you can take these at the same time as your Imnovid®
- Dexamethasone is usually only taken for a few days each week. Follow the instructions from your doctor/pharmacist carefully

What to do if you have taken more than the prescribed dose of Imnovid®:
If you accidentally take too many capsules, contact your doctor immediately.
Taking other medicines
Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines bought without a prescription. If you are seeing a different doctor or other healthcare professional for treatment (your dentist for example) you should tell them that you are taking Imnovid® and dexamethasone.

How to store Imnovid safely
• Keep your Imnovid in a safe place out of the reach and sight of children.
• Keep your Imnovid® capsules in the original box at room temperature.
• Do not use after the expiry date written on the box.

End of Treatment Requirements
After completing your Imnovid® treatment, it is important that:
• You return any unused Imnovid® capsules to your pharmacist
• You do not donate blood for 7 days.
• You do not donate semen or sperm for 7 days
• If you have been using an effective pregnancy prevention method, you must continue doing so for 7 days
• If your female partner has been using an effective pregnancy prevention method, she must continue doing so for 4 weeks.

Pregnancy Prevention Programme
• In order to ensure that an unborn baby is not exposed to Imnovid, you doctor will complete a Prescription Authorisation Form documenting that you have been informed of the requirement for your partner NOT to become pregnant during treatment with Imnovid and for one month after you finish Imnovid®.

• You should not donate blood or semen or sperm during treatment, during dose interruptions and for 7 days after treatment finishes

• Imnovid® passes into human semen. If your partner is pregnant or able to become pregnant, and she doesn’t use effective contraception, you must use condoms every time you have heterosexual activity, during treatment, during dose interruptions and for 7 days after the end of treatment even if you have had a vasectomy as seminal fluid may still contain pomalidomide in the absence of spermatozoa.

• If your partner does become pregnant whilst you are taking or 7 days after you have stopped taking Imnovid®, you should inform your treating doctor immediately and your partner should also consult her doctor immediately.
Treatment Initiation Forms

There are three versions of this form, depending on whether your patient is a woman of childbearing potential, woman of non-childbearing potential, or male. Complete these forms before prescribing Imnovid® to your patients.
Imnovid®

Pregnancy Prevention Programme

Male Treatment Initiation Form

UK
Introduction
This Treatment Initiation Form must be completed for each male patient prior to the initiation of their Immodiv™ treatment. Retain a copy of this form with their medical records, and provide a photocopy to the patient.

The aim of the Treatment Initiation Form is to protect patients and any possible fortuses by ensuring that patients are fully informed of and understand the risk of teratogenicity and other adverse effects associated with the use of Immodiv.

It does not absolve anybody from his/her responsibilities with regard to the safe use of the product and prevention of foetal exposure. This Treatment Initiation Form must be completed for each male patient prior to the initiation of their Immodiv treatment. The form should be retained with their medical records, and a copy provided to the patient.

Warning: Severe life-threatening birth defects. If Immodiv™ is taken during pregnancy it can cause severe birth defects or death to an unborn baby.

Prescriber Confirmation
I have fully explained to the patient named above the nature, purpose and risks of the treatment associated with Immodiv™, especially the risks to women of childbearing potential. I will comply with all my obligations and responsibilities as the prescribing physician of Immodiv™

| Prescriber First Name: |  |
| Prescriber Last Name: |  |
| Prescriber Signature: | Date: DD MM YYYY |

Patient: please read thoroughly and initial the adjacent box if you agree with the statement

- I understand that Pomalidomide is structurally related to thalidomide, which is known to cause severe life-threatening birth defects, therefore Immodiv™ is expected to be harmful to the unborn child.
- I understand that severe birth defects can occur with the use of Immodiv. I have been warned by my doctor that any unborn baby has a high risk of birth defects and could even die if a woman is pregnant or becomes pregnant while taking Immodiv™.
- I have been told by my doctor that I must NEVER have unprotected heterosexual contact with women who are pregnant, or may become pregnant, while I am taking Immodiv and for 7 days after stopping treatment (even if I have had a vasectomy), unless the woman is practicing effective contraception.
- I agree to use condoms during sexual activity throughout treatment duration, during dose interruption, and for 7 days after cessation of treatment if my partner is pregnant or a woman of childbearing potential not using effective contraception (even if I have had a vasectomy as seminal fluid may still contain pomalidomide in the absence of spermatozoa).
- I know that I must inform my doctor immediately if I think that my partner may be pregnant while I am taking Immodiv or 7 days after I have stopped taking Immodiv™ and my partner should referred to a physician specialized or experienced in teratology for evaluation and advice.
- I understand that Immodiv™ will be prescribed ONLY for me. I must not share it with ANYONE.
- I have read the Immodiv Patient Booklet and understand the contents, including the information about other possible important health problems related to Immodiv™,
- I understand that I cannot donate blood, semen or sperm during treatment while taking Immodiv™ (including dose interruptions) or for 7 days after stopping treatment.
- I understand that I must return any unused Immodiv™ capsules to my pharmacy at the end of my treatment.

Patient Signature: Date: DD MM YYYY
Imnovid®

Pregnancy Prevention Programme

Woman of Childbearing Potential
Treatment Initiation Form

UK
Introduction
This Treatment Initiation Form must be completed for each female patient of childbearing potential prior to the initiation of their Innovoid® treatment. Retain a copy of this form with their medical records, and provide a photocopy to the patient. It is mandatory that women of childbearing potential receive counselling and education to be made aware of the risks of Innovoid. Innovoid is contraindicated in women of childbearing potential unless all terms of counselling are met.

The aim of the Treatment Initiation Form is to protect patients and any possible foetuses by ensuring that patients are fully informed of and understand the risk of teratogenicity and other adverse effects associated with the use of Innovoid. It does not absolve anybody from his/her responsibilities with regard to the safe use of the product and prevention of foetal exposure.

Warning: Severe life-threatening birth defects. If Innovoid® is taken during pregnancy it can cause severe birth defects or death to an unborn baby.

Patient Details
| Patient First Name: |  |  |  |
| Patient Last Name: |  |  |  |
| Date of Birth: DD MM YYYY | Counselling Date: DD MM YYYY |

Pregnancy Prevention Referral
| Pregnancy prevention referral required | YES | NO |
| Pregnancy prevention referral made | DD MM YYYY |
| Pregnancy prevention consultation conducted on | DD MM YYYY |

Pregnancy Prevention
| The patient has been established on one of the following for at least 4 weeks |
| Implant | Tick |
| Levonorgestrel-releasing intrauterine system (LUS) | Tick |
| Medroxyprogesterone acetate depot | Tick |
| Tubal sterilization | Tick |
| Sexual intercourse with a vasectomised male partner only; vasectomy must be confirmed by two negative semen analyses | Tick |
| Ovulation inhibitory progesterone-only pills (i.e. desogestrel) | Tick |
| Committed to complete and absolute abstinence | Tick |

Pregnancy Test
| Date of last negative pregnancy test: DD MM YYYY |

Innovoid® treatment cannot start until the patient has been established on effective method of pregnancy prevention for 4 weeks, or commits to complete and continuous abstinence, and obtains a negative pregnancy test.

Prescriber Confirmation
I have fully explained to the patient named above the nature, purpose and risks of the treatment associated with Innovoid®, especially the risks to women of childbearing potential. I will comply with all my obligations and responsibilities as the prescribing physician of Innovoid®.

| Prescriber First Name: |  |  |
| Prescriber Last Name: |  |  |
| Date: DD MM YYYY |

Patient: please read thoroughly and initial the adjacent box if you agree with the statement

- I understand that Posaide is structurally related to thalidomide, which is known to cause severe life-threatening birth defects, therefore Innovoid is expected to be harmful to the unborn child.
- I understand that severe birth defects can occur with the use of Innovoid. I have been warned by my doctor that any unborn baby has a high risk of birth defects and could even die if a woman is pregnant or becomes pregnant while taking Innovoid
- I understand that I must not take Innovoid if I am pregnant or plan to become pregnant.
- I understand that I must use one effective method of contraception without interruption, for at least 4 weeks before starting treatment, throughout the entire duration of treatment and even in case of dose interruptions, and for at least 4 weeks after the end of treatment, or commit to absolute and continuous sexual abstinence confirmed on a monthly basis. An effective method of contraception must be initiated by an appropriately trained healthcare professional.
- I understand that if I need to change or stop my method of pregnancy prevention I will discuss this first with the physician prescribing my pregnancy prevention method and the physician prescribing my Innovoid
- I understand that I must immediately stop taking Innovoid and inform my treating doctor immediately upon suspicion of pregnancy while taking this drug (including dose interruptions); or if I miss my menstrual period or experience any unusual menstrual bleeding; or think FOR ANY REASON that I may be pregnant.
- I understand that Innovoid will be prescribed ONLY for me, I must not share it with ANYONE.
- I have read the Innovoid Patient Booklet and understand the contents, including the information about other possible important health problems related to Innovoid.
- I know that I cannot donate blood while taking Innovoid (including dose interruptions) for 7 days after stopping treatment.
- I understand that I must return any unused Innovoid capsules to my pharmacy at the end of my treatment.

Patient Confirmation
I confirm that I understand and will comply with the requirements of the Innovoid® Pregnancy Prevention Programme, and I agree that my doctor can initiate my treatment with Innovoid®.

| Patient Signature: |  |  |
| Date: DD MM YYYY |

*Innovoid® Pregnancy Prevention Programme*
Imnovid®

Pregnancy Prevention Programme

Woman of Non-Childbearing Potential Treatment Initiation Form

UK
Introduction

It is mandatory that women of non-childbearing potential receive counselling and education to be made aware of the risk of Innovid. The aim of the Treatment Initiation Form is to protect patients and any possible foetuses by ensuring that patients are fully informed of and understand the risk of teratogenicity and other adverse effects associated with the use of Innovid. It does not absolve anybody from his/her responsibilities with regard to the safe use of the product and prevention of foetal exposure.

This Treatment Initiation Form must be completed for each female patient of non-childbearing potential prior to the initiation of their Innovid treatment. The form should be retained with their medical records, and a copy provided to the patient.

Warning: Severe life-threatening birth defects. If Innovid® is taken during pregnancy it can cause severe birth defects or death to an unborn baby.

Patient Details

| Patient First Name: | | | | |
|-------------------|--------------|---------|
| Patient Last Name: | | | | |
| Date of Birth: DD MM YYYY | Counseling Date: DD MM YYYY |

Prescriber Confirmation

I have fully explained to the patient named above the nature, purpose and risks of the treatment associated with Innovid®, especially the risks to women of childbearing potential.

I will comply with all my obligations and responsibilities as the prescribing physician of Innovid.

<table>
<thead>
<tr>
<th>Prescriber First Name:</th>
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<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Prescriber Last Name:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Prescriber Signature:</td>
<td>Date: DD MM YYYY</td>
<td></td>
</tr>
</tbody>
</table>

Patient: please read thoroughly and initial the adjacent box if you agree with the statement

I understand that Pomalidomide is structurally related to thalidomide, which is known to cause severe life-threatening birth defects, therefore Innovid® is expected to be harmful to the unborn child.

I understand that severe birth defects can occur with the use of Innovid®. I have been warned by my doctor that any unborn baby has a high risk of birth defects and could even die if a woman is pregnant or becomes pregnant while taking Innovid®.

I understand that Innovid® will be prescribed ONLY for me. I must not share it with anyone.

I have read the Innovid® Patient Booklet and understand the contents, including the information about other possible important health problems related to Innovid®.

I understand that I cannot donate blood while taking Innovid® (including dose interruptions) or for 7 days after stopping treatment.

I understand that I must return any unused Innovid® capsules to my pharmacy at the end of my treatment.

<table>
<thead>
<tr>
<th>Patient Confirmation</th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Patient Signature:</td>
<td>Date: DD MM YYYY</td>
<td></td>
</tr>
</tbody>
</table>

Patient Confirmation

I confirm that I understand and will comply with the requirements of the Innovid® Pregnancy Prevention Programme, and I agree that my doctor can initiate my treatment with Innovid®.

| Patient Signature: | Date: DD MM YYYY |
Prescription Tools
Contains prescription authorisation forms to document that safety measures have been performed prior to prescribing Imnovid®. Also contains patient pocket information cards that your patients may present to other healthcare professionals to inform them about core information regarding their Imnovid® treatment.
**Prescription Authorisation Form (PAF) completion guide - Dual Format**

This guide will help you to complete the Innovid® Prescription Authorisation Form. The form is in the Healthcare Professional’s Information Pack and the 'How-to Guide' for Pharmacists, and must be completed each time you prescribe Innovid® for all patients.

<table>
<thead>
<tr>
<th>Instructions for prescribers</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Print the full hospital name where the patient is treated.</td>
</tr>
<tr>
<td>2. Print the patient’s date of birth and initials. If the middle initial is not known please use an underscore (e.g. J_S for John Smith). Do not provide confidential information (e.g. Patient Name and Hospital Number).</td>
</tr>
<tr>
<td>3. Print your name clearly.</td>
</tr>
<tr>
<td>4. Print the diagnosis – this will allow an assessment of the clinical usage of Innovid®, which is important for ongoing monitoring of the appropriateness of the Pregnancy Prevention Programme.</td>
</tr>
<tr>
<td>5. Please tick this box if the patient is a private patient and not receiving treatment through the NHS.</td>
</tr>
<tr>
<td>6. Enter the capsule strength and the patient’s treatment cycle number – this should be completed for ALL patients, irrespective of the diagnosis.</td>
</tr>
<tr>
<td>7. Complete this section appropriately to indicate that counselling and appropriate pregnancy prevention has occurred. This is a requirement of the Pregnancy Prevention Programme.</td>
</tr>
<tr>
<td>8. For women of childbearing potential you must provide a valid negative pregnancy test date (within 3 days prior to prescribing). If this is not the case Innovid® must not be dispensed.</td>
</tr>
<tr>
<td>9. You must sign, date and print your name to declare that all steps have been observed and that you authorise the prescription.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Instructions for pharmacists</th>
</tr>
</thead>
<tbody>
<tr>
<td>A. Check that all relevant sections of the form have been fully completed by the prescriber.</td>
</tr>
<tr>
<td>a. Counselling and pregnancy prevention measures must be in place</td>
</tr>
<tr>
<td>b. The prescription and prescriber signature dates must be the same</td>
</tr>
<tr>
<td>c. Innovid® can only be dispensed within 7 days of the prescription date</td>
</tr>
<tr>
<td>d. Only one month’s supply for women of childbearing potential, or three month’s supply for all other patients, of Innovid® can be dispensed at any one time, without prior agreement from Celgene.</td>
</tr>
<tr>
<td>e. The diagnosis, capsule strength and cycle number have been provided</td>
</tr>
<tr>
<td>B. Check the form does not contain confidential information (e.g. Patient Name and Hospital Number) – Celgene will not accept PAFs that do not maintain patient anonymity.</td>
</tr>
<tr>
<td>C. Check the form is complete and legible - Celgene will request that ALL incomplete or illegible forms are resent.</td>
</tr>
<tr>
<td>D. You must sign, date and print your name to declare that the form has been completed fully and dispensing is taking place within 7 days of the date of prescription.</td>
</tr>
<tr>
<td>E. Complete the “Date faxed to Celgene” and “Faxed by (Name)” fields and FAX completed forms to Celgene on 0808 100 9910.</td>
</tr>
</tbody>
</table>

**Further information and materials are available from Celgene.**
Website: www.celgene.co.uk  E-mail: rmp.uk.ire@celgene.com
Pregnancy Prevention Programme: 0808 156 3059

UK-POM130015a
Imnovid® Prescription Authorisation Form

Name of treating Hospital

Patient Date of Birth: D D M M Y Y Y Y
Patient ID Number/Initials

Prescribing physician: (print)

Diagnosis: (tick) Relapsed and Refractory Multiple Myeloma ☐
Other ☐ [If other please specify]

If this patient is being treated privately, tick here ☐

Capsule strength prescribed: (tick) 1mg ☐ 2mg ☐ 3mg ☐ 4mg ☐
Quantity of Capsules per cycle prescribed:*
Number of cycle(s) prescribed 1 ☐ 2 ☐ 3 ☐
Total number of capsules:
* Do NOT enter number of Packs

Exceptional Dispensing: (tick if applicable) Yes ☐

Please enter the cycle number(s) of Imnovid® prescribed for this patient

Woman of non-childbearing potential

Male

The patient has been counselled about the teratogenic risk of treatment with Imnovid® and understands the need to use a condom if involved in sexual activity with a woman of childbearing potential (even if the patient has had a vasectomy).

Note to pharmacist – do not dispense unless ticked

Woman of childbearing potential (maximum 4 weeks prescription only)

The patient has been counselled about the teratogenic risk of treatment and the need to avoid pregnancy, and has been on effective contraception for at least 4 weeks?

Date of last negative pregnancy test: D D M M Y Y Y Y

Note to pharmacist – do not dispense unless ticked and a negative test has been conducted within 3 days prior of the prescription date

FAX the completed form to Celgene on 0808 100 9910

Date faxed to Celgene: D D M M Y Y Y Y
Faxed by (Name)

Both signatures must be present prior to dispensing Imnovid®

Prescriber’s declaration
I am a physician experienced in managing anti-cancer therapies and I have read and understood the Imnovid® Healthcare Professional’s Information Pack and confirm that the patient has signed an informed consent for Imnovid® treatment.

Sign
Date D D M M Y Y Y Y
Bleep

Print

Note to pharmacist – prescription and Prescription Authorisation Form must have the same date

Pharmacist’s declaration
I am satisfied that this Imnovid® Prescription Authorisation Form has been completed fully, confirm that dispensing is taking place within 7 days of the date of prescription and that I have read and understood the Imnovid® Healthcare Professional’s Information Pack.

Sign
Date D D M M Y Y Y Y
Bleep

Print

Name and postcode of dispensing pharmacy

Home delivery information
Name and postcode of Home delivery company used, if applicable.
Emergency contact phone numbers:

Emergency contact:

Office hours:

Out of hours:

Further information for patients, carers and healthcare professionals, on Imnovid, its side effects and pregnancy prevention, can be found at www.celgene.co.uk

Imnovid®▼ (pomalidomide)
Information for patients:

You MUST tell your doctor immediately if you experience:

• any fever, chills, sore throat, cough, mouth ulcers or any other symptoms of infection
• any bleeding or bruising in the absence of injury
• any chest or leg pain and swelling
• any shortness of breath.
• Any other symptom that causes concern

You MUST inform your doctor immediately if you suspected that you or your female partner is pregnant.
Information for patients and health care professionals:

Imnovid is an immunomodulator and is an expected human teratogen therefore;

- Female patients of childbearing potential must always use effective contraception and male patients with pregnant partners or partners of childbearing potential not using effective contraception must always use condoms (even if man has had vasectomy).
- Female patients of childbearing potential must have regular pregnancy tests to ensure that they are not pregnant.
- If a female patient or female partner of a male patient suspects they are pregnant they must contact their physician immediately.

Information for health care professionals:

This patient is receiving Imnovid (pomalidomide) for the treatment of relapsed and refractory multiple myeloma (MM) who have received at least two prior treatment regimens, including both lenalidomide and bortezomib. This patient is at risk of:

- Neutropenia
- Thrombocytopenia
- Thromboembolism

They should receive immediate assessment and treatment if experiencing any of the symptoms described overleaf.
Complete these forms if your patient experiences an adverse event or becomes pregnant while being treated with Imnovid®, and send the information to the Celgene Drug Safety department.
Adverse Event Report

Reporter's details

<table>
<thead>
<tr>
<th>Title: Mr, Mrs, Miss, Ms, Dr. etc</th>
<th>First Name(s):</th>
</tr>
</thead>
<tbody>
<tr>
<td>Job Title:</td>
<td></td>
</tr>
<tr>
<td>Address:</td>
<td></td>
</tr>
<tr>
<td>City, town:</td>
<td>County:</td>
</tr>
<tr>
<td>Post code:</td>
<td>Country:</td>
</tr>
<tr>
<td>Phone Number:</td>
<td>Fax Number:</td>
</tr>
<tr>
<td>Email address:</td>
<td></td>
</tr>
</tbody>
</table>

Patient information

<table>
<thead>
<tr>
<th>Patient ID (initials):</th>
<th>Age:</th>
<th>Date of Birth DD MM YYYY</th>
</tr>
</thead>
<tbody>
<tr>
<td>Weight (Kg):</td>
<td>Height (cm):</td>
<td></td>
</tr>
</tbody>
</table>

Adverse event

<table>
<thead>
<tr>
<th>Overall diagnosis of the event</th>
</tr>
</thead>
<tbody>
<tr>
<td>Event onset date DD MM YYYY</td>
</tr>
<tr>
<td>Event stop date DD MM YYYY</td>
</tr>
<tr>
<td>Or ongoing at time of reporting (if less than 24 hours) HR MIN</td>
</tr>
</tbody>
</table>

Description of adverse event

| Symptoms and treatment |

Outcome of adverse event

<table>
<thead>
<tr>
<th>Recovered</th>
<th>Recovered with sequelae</th>
<th>Not recovered</th>
<th>Unknown</th>
<th>Death</th>
</tr>
</thead>
<tbody>
<tr>
<td>Date of death DD MM YYYY</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Possible cause of death</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

If autopsy is performed please forward report. Please attach relevant clinical laboratory assessments to confirm the event.

Seriousness of adverse event (tick all that apply)

<table>
<thead>
<tr>
<th>Death</th>
<th>Life-threatening</th>
<th>Hospitalisation or prolonged hospitalisation</th>
<th>Persistent or significant disability or incapacity</th>
<th>Congenital anomaly/birth defect</th>
<th>Other medically important condition or event</th>
<th>Non-serious</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
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<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

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Celgene Limited
1 Longwalk Road, Stockley Park
Uxbridge
UB11 1DB
United Kingdom
Tel: 08082 389 908
Fax: 08448 010 468
Email: drugsafetyuk@celgene.com
Adverse Event Report

Medical history (May be supplied as a copy of Medical file if up to date)

Current or past relevant medical history (including concurrent illness, allergy, smoking, alcohol abuse)

If YES please specify

Suspect drug

<table>
<thead>
<tr>
<th>Drug, Dosage-form, Strength, Route (eg. Tab 5mg, oral)</th>
<th>Dose &amp; frequency</th>
<th>Batch no.</th>
<th>Therapy Start date</th>
<th>Therapy Stop date</th>
<th>Causal relationship</th>
<th>Indication for use of drug</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td>DD    MM   YYYY</td>
<td>DD    MM   YYYY</td>
<td>1 = Not related</td>
<td>2 = Related</td>
</tr>
<tr>
<td></td>
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<td>DD    MM   YYYY</td>
<td>DD    MM   YYYY</td>
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<td>DD    MM   YYYY</td>
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<td></td>
<td>DD    MM   YYYY</td>
<td>DD    MM   YYYY</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

OTHER MEDICATION

(Medication taken during the past 3 months prior to the event - May be supplied as a copy of Medical file if up to date)

<table>
<thead>
<tr>
<th>Drug, Dosage-form, Strength, Route (eg. Tab 5mg, oral)</th>
<th>Dose &amp; frequency</th>
<th>Therapy Start date</th>
<th>Therapy Stop date</th>
<th>Causal relationship</th>
<th>Indication for use of drug</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>DD    MM   YYYY</td>
<td>DD    MM   YYYY</td>
<td>1 = Not related</td>
<td>2 = Related</td>
</tr>
<tr>
<td></td>
<td></td>
<td>DD    MM   YYYY</td>
<td>DD    MM   YYYY</td>
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<tr>
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<td>DD    MM   YYYY</td>
<td>DD    MM   YYYY</td>
<td></td>
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</tr>
<tr>
<td></td>
<td></td>
<td>DD    MM   YYYY</td>
<td>DD    MM   YYYY</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Action taken, suspect drug

- Continued unchanged  
- Continued, dose or dose regimen changed  
- Please specify if dose or dose regimen changed:

Notification

- Initial report  
- Final report  
- Follow-up report  

Name:

Title:

Signature:

UK-PDM130015a
Pregnancy Reporting Form

Please complete this form to report a pregnancy in a patient (or in a female partner of a male patient) treated with Imnovid®.

As part of Celgene’s Safety Monitoring System, it is essential that we follow-up on all reported pregnancies. Celgene will therefore be in contact with you for further information in due course and would value your co-operation to ensure we are able to obtain all relevant information regarding foetal exposure to our products.

Please fax or email immediately to Celgene Drug Safety at the number/address below:

Celgene Drug Safety:  Tel: 08082 389 908  
Fax: 08448 010 468  
Email: drugsafetyuk@celgene.com  

Celgene Limited  
1 Longwalk Road, Stockley Park  
Uxbridge, UB11 1DB, United Kingdom

<table>
<thead>
<tr>
<th>Reporter's Details</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Title:</strong> Mr, Mrs, Miss, Ms, Dr. etc</td>
</tr>
<tr>
<td><strong>Job Title:</strong></td>
</tr>
<tr>
<td><strong>Address:</strong></td>
</tr>
<tr>
<td><strong>Post code:</strong></td>
</tr>
<tr>
<td><strong>Phone Number:</strong></td>
</tr>
<tr>
<td><strong>Email address:</strong></td>
</tr>
<tr>
<td><strong>Patient ID:</strong></td>
</tr>
<tr>
<td><strong>Female partner of male patient information</strong></td>
</tr>
<tr>
<td><strong>Patient ID:</strong></td>
</tr>
<tr>
<td><strong>Exposure of a pregnant female - not patient or partner</strong></td>
</tr>
<tr>
<td><strong>Patient ID:</strong></td>
</tr>
<tr>
<td><strong>Patient treatment information: Revlimid capsule</strong></td>
</tr>
<tr>
<td><strong>Batch No.:</strong></td>
</tr>
<tr>
<td><strong>Start Date:</strong></td>
</tr>
<tr>
<td><strong>Indication for use:</strong></td>
</tr>
<tr>
<td><strong>Date of last menses:</strong></td>
</tr>
<tr>
<td><strong>Pregnancy information</strong></td>
</tr>
<tr>
<td><strong>Has the pregnancy been confirmed?</strong></td>
</tr>
<tr>
<td><strong>Estimated gestational stage:</strong></td>
</tr>
<tr>
<td><strong>Has the patient already been referred to an obstetrician/gynaecologist?</strong></td>
</tr>
<tr>
<td><strong>If yes, please specify his/her name and contact detail</strong></td>
</tr>
<tr>
<td><strong>Name:</strong></td>
</tr>
<tr>
<td><strong>Reporter</strong></td>
</tr>
<tr>
<td><strong>Signature:</strong></td>
</tr>
</tbody>
</table>

UK-PDM130015a
## Background Information on Reason for Pregnancy

<table>
<thead>
<tr>
<th>Was patient erroneously considered not to be of child bearing potential</th>
<th>Yes</th>
<th>No</th>
</tr>
</thead>
</table>

### If yes, state reason for considering not to be of childbearing potential

- **a.** Age $\geq 50$ years and naturally amenorrhoeic* for $\geq 1$ year  
  *amenorrhoea following cancer therapy or during lactation does not rule out childbearing potential
- **b.** Premature ovarian failure confirmed by a specialist gynaecologist
- **c.** Previous bilateral salpingo-oophorectomy, or hysterectomy
- **d.** XY genotype, Turner syndrome, uterine agenesis.

### Indicate from the list below what contraception was used

- **a.** Implant
- **b.** Levonorgestrel-releasing intrauterine system (IUS)
- **c.** Medroxyprogesterone acetate depot
- **d.** Tubal sterilization (specify below)  
  - I. Tubal ligation  
  - II. Tubal diathermy  
  - III. Tubal clips
- **e.** Sexual intercourse with a vasectomised male partner only; vasectomy must be confirmed by two negative semen analyses
- **f.** Ovulation inhibitory progesterone-only pills (i.e., desogestrel)
- **g.** Other progesterone-only pills
- **h.** Combined oral contraceptive pill
- **i.** Other intra-uterine devices
- **j.** Condoms
- **k.** Cervical cap
- **l.** Sponge
- **m.** Withdrawal
- **n.** Other
- **o.** None

### Indicate from the list below the reason for contraceptive failure

- Missed oral contraception
- Other medication or intercurrent illness interacting with oral contraception
- Identified mishap with barrier method
- Unknown
- Had the patient committed to complete and continuous abstinence
- Was pomalidomide started despite patient already being pregnant
- Did patient receive educational materials on the potential risk of teratogenicity
- Did patient receive instructions on need to avoid pregnancy
## Prenatal Information

<table>
<thead>
<tr>
<th>Date of last menstrual period:</th>
<th>Estimated Delivery Date:</th>
</tr>
</thead>
</table>

## PREGNANCY TEST

<table>
<thead>
<tr>
<th>Urine Qualitative</th>
<th>Reference Range</th>
<th>Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>Serum quantitative</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

## Past Obstetric History

<table>
<thead>
<tr>
<th>Year of pregnancy</th>
<th>Outcome</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Spontaneous abortion</td>
</tr>
<tr>
<td></td>
<td>No</td>
</tr>
</tbody>
</table>

## Birth Defects

<table>
<thead>
<tr>
<th>Was there any birth defect from any pregnancy</th>
<th>Yes</th>
<th>No</th>
<th>Unknown</th>
</tr>
</thead>
<tbody>
<tr>
<td>Is there any family history of any congenital abnormality abstinence</td>
<td>Yes</td>
<td>No</td>
<td>Unknown</td>
</tr>
<tr>
<td>If yes to either of these questions, please provide details below:</td>
<td>Yes</td>
<td>No</td>
<td>Unknown</td>
</tr>
</tbody>
</table>

## Maternal Past Medical History

<table>
<thead>
<tr>
<th>Condition</th>
<th>Dates</th>
<th>Treatment</th>
<th>Outcome</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>From</td>
<td>To</td>
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</tbody>
</table>

UK-POM130015a
### Maternal Current Medical Conditions

<table>
<thead>
<tr>
<th>Condition</th>
<th>From</th>
<th>Treatment</th>
</tr>
</thead>
<tbody>
<tr>
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</tbody>
</table>

### Maternal Social History

<table>
<thead>
<tr>
<th>Yes</th>
<th>No</th>
</tr>
</thead>
</table>

#### Alcohol
If yes, amount/units per day: 

#### Tobacco
If yes, amount per day: 

#### IV or recreational drug use
If yes, provide details

### MATERNAL MEDICATION DURING PREGNANCY AND IN 4 WEEKS BEFORE PREGNANCY
(including herbal, alternative and over the counter medicines and dietary supplements)

<table>
<thead>
<tr>
<th>Medication/treatment</th>
<th>Start Date</th>
<th>Stop Date/Continuing</th>
<th>Indication</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
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<td></td>
</tr>
</tbody>
</table>

**Name of person completing this form**

<table>
<thead>
<tr>
<th>Signature</th>
<th>Date</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Treatment checklists and algorithms
Combined checklist for commencing Imnovid®

This checklist is to assist you with counseling a patient before they commence Imnovid treatment in order to assure it is used safely and correctly. Please choose the applicable column for the risk category of the patient and refer to the counseling messages provided.

<table>
<thead>
<tr>
<th>Did you inform your patient:</th>
<th>Male Patients</th>
<th>Women of Non-Childbearing Potential*</th>
<th>Women Childbearing Potential</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Of the expected teratogenic risk to the unborn child?</td>
<td></td>
<td></td>
<td>N/A</td>
</tr>
<tr>
<td>• Of the need for effective contraception** 4 weeks before starting treatment, during treatment interruption, throughout the entire duration of treatment and for 4 weeks after the end of treatment, or absolute and continued abstinence?</td>
<td>N/A</td>
<td></td>
<td>N/A</td>
</tr>
<tr>
<td>• That she must comply with advice on contraception even if she has amenorrhea?</td>
<td>N/A</td>
<td></td>
<td>N/A</td>
</tr>
<tr>
<td>• Which are the effective contraceptive methods that she or the female partner of a male patient can use?</td>
<td></td>
<td></td>
<td>N/A</td>
</tr>
<tr>
<td>• Of the expected consequences of pregnancy and the need to stop treatment and consult rapidly if there is a risk of pregnancy?</td>
<td></td>
<td></td>
<td>N/A</td>
</tr>
<tr>
<td>• Of the need to use condoms, including those who have had a vasectomy as seminal fluid may still contain pomalidomide in the absence of spermatozoa, throughout treatment duration, during dose interruption, and for 7 days after cessation of treatment if partner is pregnant or of childbearing potential not using effective contraception?</td>
<td></td>
<td></td>
<td>N/A</td>
</tr>
<tr>
<td>• Of the need not to donate semen or sperm during treatment (including during dose interruptions) and for 7 days following discontinuation</td>
<td></td>
<td></td>
<td>N/A</td>
</tr>
<tr>
<td>• Of the hazards and necessary precautions associated with use of pomalidomide?</td>
<td></td>
<td></td>
<td>N/A</td>
</tr>
<tr>
<td>• Not to share medication?</td>
<td></td>
<td></td>
<td>N/A</td>
</tr>
<tr>
<td>• To return unused capsules to pharmacist?</td>
<td></td>
<td></td>
<td>N/A</td>
</tr>
<tr>
<td>• Not to donate blood whilst taking pomalidomide, during treatment interruptions and for 7 days following discontinuation?</td>
<td></td>
<td></td>
<td>N/A</td>
</tr>
<tr>
<td>• About the thromboembolic risk and the possible requirement to take thromboprophylaxis during treatment with pomalidomide?</td>
<td></td>
<td></td>
<td>N/A</td>
</tr>
<tr>
<td>Can you confirm that your patient:</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>• Was referred to a contraceptive consultant, if required?</td>
<td>N/A</td>
<td></td>
<td></td>
</tr>
<tr>
<td>• Is capable of complying with contraceptive measures?</td>
<td></td>
<td></td>
<td>N/A</td>
</tr>
<tr>
<td>• Agreed to undergo pregnancy testing at 4 weekly intervals unless confirmed tubal sterilization?</td>
<td>N/A</td>
<td></td>
<td></td>
</tr>
<tr>
<td>• Had a negative pregnancy test before starting treatment even if absolute and continued abstinence?</td>
<td>N/A</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

*Refer to the Healthcare Professional Information Booklet for criteria to determine if patient is a woman of non-childbearing potential.

** Refer to ‘PPP Advice for Women of Child Bearing Potential’ section in the Healthcare Professional Information Booklet for information on contraception.

TREATMENT FOR A WOMAN OF CHILDBEARING POTENTIAL CANNOT START UNTIL PATIENT IS ESTABLISHED ON EFFECTIVE METHOD OF CONTRACEPTION FOR 4 WEEKS OR Commits TO COMPLETE AND CONTINUED ABstinence AND PREGNANCY TEST IS NEGATIVE
Algorithm for implementation of Pregnancy Prevention Programme

Evaluation of new patient

Female

Without childbearing potential (at least one criterion must be fulfilled)

With childbearing potential

If not already practising effective contraception start adequate contraception at appropriate time, based on the method used and menstrual cycle. Unless practising complete and continued abstinence

- Either implant, Levonorgestrel-releasing intrauterine system, medroxyprogesterone acetate depot, tubal sterilisation, vasectomised partner, ovulation inhibitory progesterone only pill (desogestrel)
- Contraception continues during treatment and for 4 weeks after treatment discontinuation

Test for pregnancy (minimum sensitivity of 25mlU/ml) after 4 weeks of effective contraception (even if sexual abstinence)

Negative

Start Innovid® treatment. Pregnancy testing at 4 weekly intervals (even if sexual abstinence)

Positive

DO NOT START INNOVID®. Refer to appropriately trained healthcare professional

Start Innovid® treatment. Contraception and pregnancy testing not required

Male

With childbearing potential

Age > 50 years and naturally amenorrhoeic for > 1 year (amenorrhoea following cancer therapy or during lactation does not rule out childbearing potential)

- Previous bilateral salpingo-oophorectomy or hysterectomy
- Premature ovarian failure confirmed by a specialist
- XY genotype, Turners syndrome or uterine agenesis

Start Innovid®. Condom required for sexual activity (even if vasectomised) for the duration of Innovid® treatment, including dose interruptions, and for 7 days after treatment if partner is pregnant or a woman of childbearing potential who is not practicing effective contraception

Previous bilateral salpingo-oophorectomy or hysterectomy

Premature ovarian failure confirmed by a specialist

XY genotype, Turners syndrome or uterine agenesis

UK-POM130015a
Pharmacy registration and dispensing of Imnovid®

1. Identify patient for Imnovid®, obtain Healthcare Professional’s Information Pack from Celgene

2. Read Pack, fax Pharmacy Registration Form to Celgene

3. Counsel patient:
   - Pregnancy prevention
   - Complete Treatment Initiation Form
   - Complete Prescription Authorisation Form
   - Provide patient educational materials

4. Order Imnovid®

Patient presents at pharmacy, pharmacist:
- Cross-checks Prescription Authorisation Form
- Signs Prescription Authorisation Form
- Dispenses Imnovid® to patient
- Sends copy of Prescription Authorisation Form to Celgene
Where can I get further copies of the Imnovid® Healthcare Professional’s Information Pack or the patient materials?

The CD provided with the Imnovid® Healthcare Professional’s Information Pack contains electronic versions of all the forms and may be used to print out further copies. The materials can also be downloaded from the Celgene website (www.celgene.co.uk).

If you would like further copies of the Imnovid® Healthcare Professional’s Information Pack or any other materials for healthcare professionals or patients, please telephone or e-mail Celgene using the contact details below, or by speaking to any Celgene representative.

Tel: 0808 156 3059
Fax: 0808 156 3058
Email: rmp.uk.ire@celgene.com
Web: www.celgene.co.uk

What must I do prior to ordering or dispensing Imnovid®?

All pharmacies must register with Celgene prior to ordering or dispensing Imnovid®. You will need to register the dispensing pharmacy using the Pharmacy Registration Form. This form is contained within this pack. Completed Pharmacy Registration Forms should be faxed to Celgene (Fax: 0808 156 3058). Once you have returned a completed Pharmacy Registration Form, we will inform the distributors who will place you on the registered list.

Do I need a registration number to order Imnovid®?

No, you just need to register with Celgene by returning the Pharmacy Registration Form. We will register you and inform the distributor that you are registered and can receive Imnovid®.

Where do I order Imnovid®?

Once registered, to order Imnovid® please contact Celgene in the UK and Northern Ireland. You must have returned the Pharmacy Registration Form to Celgene before you can place an order. You will need to fax or email your order to the distributors (all orders must be received in writing)

Distributor: Celgene Order Contact Centre (UK and Northern Ireland)
Tel: 0208 831 8483
Fax: 0208 831 8792
Email: orders-uk@celgene.com

Orders placed Mondays – Fridays before 13.30 will generally be delivered the following working day
How should I report an adverse event?

Adverse events should be reported to Celgene Drug Safety. Adverse event reporting forms are included in this Healthcare Professional’s Information Pack. Completed forms should be forwarded to the Celgene Drug Safety using the contact details below:

Tel: 0808 238 9908
Fax: 0844 801 0468
Email: drugsafetyuk@celgene.com

You may also report any adverse events to the MHRA using a ‘Yellow Card’. Reporting forms and information can be found at www.mhra.gov.uk/yellowcard.

What are the contact details for Celgene Medical Information?

To contact Celgene in the UK for medical information, please telephone or Email the Medical Information department using the contact details below:

Tel: 0844 801 0045
Fax: 0844 801 0046
Email: medinfo.uk.ire@celgene.com
CONTENTS
Contact details

Risk Management:
For information and questions on the risk management of Celgene’s products, the Pregnancy Prevention Programme and pharmacy registrations.
Tel: 0808 156 3059
Fax: 0808 156 3058
Email: rmp.uk.ire@celgene.com

Drug Safety:
To report any adverse events to Celgene.
Tel: 0808 238 9908
Fax: 0844 801 0468
Email: drugsafetyuk@celgene.com
Adverse events can also be reported to the MHRA using a ‘Yellow Card’ — reporting forms and information can be found at www.mhra.gov.uk/yellowcard.

Medical Information:
To obtain Medical Information on Celgene’s products.
Tel: 0844 801 0045
Fax: 0844 801 0046
Email: medinfo.uk.ire@celgene.com

Website:
Reference safety information (including the summary of product characteristics) and educational materials for all of Celgene’s products are available from our website - www.celgene.co.uk

Distributor:
For product delivery enquiries.

In Great Britain and Northern Ireland
Tel: 0208 831 8483
Fax: 0208 831 8792
Email: orders-uk@celgene.com