

Patient Information

ISTODAX (ISS toe dax)
(romidepsin)
for injection

Read the patient information that comes with ISTODAX before you receive your first treatment and each time before you are treated. There may be new information. This leaflet does not take the place of talking with your doctor about your medical condition or your treatment.

What is ISTODAX?

ISTODAX is a prescription medicine used to treat people with a type of cancer called cutaneous T-cell lymphoma (CTCL) or peripheral T-cell lymphoma (PTCL) after at least one other type of medicine by mouth or injection has been tried.

It is not known if ISTODAX is safe and effective in children under 18 years of age.

What should I tell my doctor before I receive ISTODAX?

Before receiving ISTODAX, tell your doctor if you:

- have any heart problems, including an irregular or fast heartbeat, or a condition called QT prolongation.
- have kidney problems
- have liver problems, including a past history of hepatitis B
- have problems with the amount of potassium or magnesium in your blood
- have nausea, vomiting, or diarrhea
- have any other medical conditions
- are pregnant or plan to become pregnant. ISTODAX may harm your unborn baby. Talk to your doctor about the best way to prevent pregnancy while receiving ISTODAX. **Tell your doctor right away if you become pregnant while receiving ISTODAX.**
- are breastfeeding or plan to breastfeed. It is not known if ISTODAX passes into your breast milk. You and your doctor should decide if you will receive ISTODAX or breastfeed. Talk to your doctor about the best way to feed your baby while you are being treated with ISTODAX.

Tell your doctor about all of the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements and any recent changes in medications.

Some medicines may affect how ISTODAX works, or ISTODAX may affect how other medicines work. Especially tell your doctor if you take or use:

- warfarin sodium (Coumadin, Jantoven) or any other blood thinner medicine. Ask your doctor if you are not sure if you are taking a blood thinner. Your doctor may want to test your blood more often.
- a medicine to treat abnormal heartbeats
- St. John's Wort (*Hypericum perforatum*)
- Dexamethasone (a steroid)
- Medicine for:
 - tuberculosis (TB)
 - seizures (epilepsy)
 - bacterial infections (antibiotics)
 - fungal infections (antifungals)
 - HIV (AIDS)
 - depression

Ask your doctor if you are not sure if your medicine is one that is listed above. Know the medicines you take. Keep a list of them and show it to your doctor and pharmacist when you get a new medicine.

How will I receive ISTODAX?

- ISTODAX will be given to you by your doctor or nurse as an intravenous (IV) injection into your vein usually over 4 hours.
- ISTODAX is usually given on Day 1, Day 8, and Day 15 of a 28-day cycle of treatment.
- Your doctor will decide how long you will receive treatment with ISTODAX.
- Your doctor will check your blood cell counts and other blood tests regularly during your treatment with ISTODAX to check for side effects of ISTODAX. Your doctor may decide to do other tests to check your health as needed.
- Your doctor may stop your treatment, change when you get your treatment, or change the dose of your treatment if you have certain side effects while receiving ISTODAX.

What are the possible side effects of ISTODAX?

ISTODAX may cause serious side effects, including:

- **Low blood cell counts:** Your doctor will regularly do blood tests to check your blood counts.
 - **Low platelets:** can cause unusual bleeding, or bruising under the skin. Talk to your doctor right away if this happens.
 - **Low red blood cells:** may make you feel tired and you may get tired easily. You may look pale, and feel short of breath. Tell your doctor if you have these symptoms.
 - **Low white blood cells:** can cause you to get infections, which may be serious.
- **Serious infections.** People receiving ISTODAX can develop serious infections that can sometimes lead to death. These infections can happen during treatment and within 30 days after treatment with ISTODAX. Your risk of infection may be higher if you have had chemotherapy in the past. Tell your doctor right away if you have any of these symptoms of infection:

○ fever	○ burning with urination
○ cough	○ flu-like symptoms
○ shortness of breath with or without chest pain	○ muscle aches
	○ worsening skin problems
- **Changes in your heartbeat.** Your doctor may check your heart by doing an ECG (electrocardiogram) and blood tests to check your potassium and magnesium levels, before you start ISTODAX treatment. Tell your doctor if you feel an abnormal heartbeat, feel dizzy or faint, have chest pain or shortness of breath.
- **Tumor Lysis Syndrome (TLS).** TLS is a problem of the rapid breakdown of cancer cells that can happen during your treatment with ISTODAX. You should drink plenty of fluids in the 3 days after you receive treatment with ISTODAX. Your doctor may do blood tests to check for TLS and may give you medicine to prevent or treat TLS.

Common side effects of ISTODAX include:

- nausea, vomiting, diarrhea, and loss of appetite
- tiredness

Tell your doctor if you have any side effect that bothers you or does not go away.

These are not all the possible side effects of ISTODAX. For more information, ask your doctor or pharmacist.

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

General information about ISTODAX

Medicines are sometimes prescribed for purposes other than those listed in a Patient Information leaflet.

This Patient Information leaflet summarizes the most important information about ISTODAX. If you would like more information, talk with your doctor. You can ask your pharmacist or doctor for information about ISTODAX that is written for health professionals.

For more information, go to www.ISTODAX.com or call 1-888-423-5436.

What are the ingredients in ISTODAX?

Active ingredient: romidepsin

Inactive ingredients: povidone. The diluent contains 80% propylene glycol and 20% dehydrated alcohol.

This Patient Information has been approved by the U.S. Food and Drug Administration.

Manufactured for:
Celgene Corporation
Summit, NJ 07901

Manufactured by:
Ben Venue Laboratories, Inc.
Bedford, OH 44146

or

Baxter Oncology GmbH
Halle/Westfalen, Germany

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