

Istodax[®]

Powder for Injection

(romidepsin 10 mg)

Consumer Medicine Information

WHAT IS IN THIS LEAFLET

This leaflet answers some common questions about Istodax.

It does not contain all the available information.

It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you taking Istodax against the benefits it is expected to have for you.

If you have any concerns about taking this medicine, ask your doctor or pharmacist.

Keep this leaflet.

You may need to read it again.

WHAT ISTODAX IS USED FOR

Istodax contains an active ingredient called romidepsin.

It is a type of anti-cancer (anti-neoplastic) medicine that belongs to a group of medicines known as histone deacetylase or HDAC inhibitors.

Istodax is used to treat a type of cancer called peripheral T-cell lymphoma, or PTCL, in patients who have received at least one previous treatment for this condition.

PTCL is a disease in which a type of white blood cell from your immune system, called T-cells, grows abnormally. Istodax works by

slowing or stopping the growth of these cancer cells. This medicine has also been shown to kill cancer cells.

Ask your doctor if you have any questions about why this medicine has been prescribed for you.

Your doctor may have prescribed Istodax for another reason.

Istodax is not addictive.

This medicine is available only with a doctor's prescription.

The safe and effective use of Istodax has not been established in children or adolescents (under 18 years of age).

BEFORE YOU ARE GIVEN ISTODAX

When you must not be given Istodax

Do not take Istodax if:

- **you are allergic to romidepsin or any of the ingredients listed at the end of this leaflet (see Product Description).**

Some of the symptoms of an allergic reaction may include:

- shortness of breath
- wheezing or difficulty breathing
- swelling of the face, lips, tongue or other parts of the body
- rash, itching or hives on the skin.

Before you are given Istodax

Tell your doctor if you have allergies to any other medicines, foods, preservatives or dyes.

Tell your doctor if:

- **you have a history of heart problems or are taking medicines used to help treat abnormal rhythms of the heart (anti-arrhythmics).**

Istodax treatment has been associated with the occurrence of abnormal heart rhythms. Your doctor may conduct a heart function (electrocardiograph [ECG]) test before and during treatment to monitor the activity of your heart.

- **you have a history of blood conditions which affect the number of blood cells in your body.**

This medicine can cause a reduction in the numbers of blood cells. Your doctor will ask you to take regular blood tests to monitor the levels of your blood cells.

- **you have a history of frequent infections, or a history of hepatitis B or Epstein Barr virus infection.**

This medicine can cause a reduction in the numbers of blood cells used by the body to fight infection. Your doctor will ask you to take regular blood tests to monitor the levels of your blood cells.

- **you are pregnant or plan to become pregnant.**

Istodax may harm your unborn baby. Your doctor can discuss with you the risks and benefits of using this medicine during pregnancy and the type of contraceptives that can be used while taking this medicine.

- **you are breast-feeding or plan to breast-feed.**

It is not known if Istodax passes into breast milk. Your doctor will help to decide if you should stop breast-feeding when you start treatment with this medicine.

- **you have a history of liver problems.**
- **you have a history of kidney problems.**
- **you have problems with the amount of potassium or magnesium in your blood.**

If you have not told your doctor about any of the above, tell them before you are given Istodax or as soon as possible after receiving it.

Taking other medicines

Tell your doctor if you are taking any other medicines, including any that you get without a prescription from your pharmacy, supermarket or health food shop.

Some medicines and Istodax may interfere with each other. These include:

- warfarin or any other blood thinner used to prevent blood clots
- medicines used to treat heart problems such as arrhythmia (irregular beating of the heart)
- medicines used to treat fungal infections (such as ketoconazole)
- medicines used to treat tuberculosis (such as rifampin)
- oestrogen-containing oral contraceptive pills for women
- St John's Wort.

These medicines may be affected by Istodax or may affect how well it works. You may need different

amounts of your medicines, or you may need to take different medicines.

Your doctor and pharmacist have more information on medicines to be careful with or avoid while taking Istodax.

HOW ISTODAX IS GIVEN

Istodax will be given to you as an intravenous (IV) infusion into your vein by your doctor or nurse.

Your doctor will choose the correct dose of Istodax for you.

- Your dose will depend on your general condition and your height and weight.
- Your dose will be calculated based on your body surface area, with the usual dose of 14 mg Istodax per metre squared of body surface area.
- Istodax will be given to you over a 4-hour period on Days 1, 8 and 15 of a 28-day cycle. These cycles may be repeated for as long as you continue to receive benefit from Istodax.
- Your doctor will check your progress and may change your dose if necessary.

Your doctor may also give you another medicine to help stop you feeling sick (nausea) and vomiting.

If you have any questions on the use of Istodax, ask your doctor.

WHILE YOU ARE BEING GIVEN ISTODAX

Things you must do

If you become pregnant while being given Istodax, tell your doctor immediately.

Tell all doctors, dentists, and pharmacists who treat you that you are being given this medicine.

If you are going to have surgery, tell the surgeon or anaesthetist that you are being given Istodax.

It may affect other medicines used during or after the surgery.

Drink plenty of fluids while taking Istodax. Discuss with your doctor how much water you should drink.

Having enough fluids may help to reduce the chances of dehydration.

Keep all of your doctor's appointments so that your progress can be checked.

Your doctor will need to perform regular ECG (heart function) tests and blood tests.

Things to be careful of

Be careful while driving or operating machinery until you know how Istodax affects you.

This medicine may cause tiredness or the feeling of weakness in some people. If you have any of these symptoms, do not drive, operate machinery or do anything else that could be dangerous.

SIDE EFFECTS

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are receiving Istodax.

Like all medicines, Istodax can have side effects, although not everybody gets them. Sometimes they are serious, most of the time they are not. You may need medical attention if you get some of the side effects.

Do not be alarmed by the following list of side effects. You may not experience any of them.

Ask your doctor or pharmacist to answer any questions you may have.

Tell your doctor or pharmacist if you notice any of the following and they worry you:

- gastro-intestinal problems such as nausea, vomiting, diarrhoea,

- constipation, stomach pain, indigestion, a loss of appetite, weight loss, or changes in taste.
- easy bleeding or bruising in the absence of injury. You may have a low number of platelets, which are the blood cells that help to clot your blood.
 - weakness, tiredness, dizziness, shortness of breath or pale colour. You may have a low number of red blood cells that carry oxygen.
 - swelling of hands, ankles or feet; muscle pain or spasms.
 - signs of dehydration such as dry mouth, increasing thirst, weakness or light-headedness.

The above list mainly includes the more common side effects of your medicine.

If any of the following happen, tell your doctor immediately or go to Accident and Emergency at your nearest hospital:

- **Sudden signs of allergy such as rash, itching or hives on the skin; swelling of the face, lips or tongue or other parts of the body; and/or shortness of breath, wheezing or trouble breathing.**
- **Symptoms of infection such as fever, chills, sore throat, cough, shortness of breath with or without chest pain, mouth ulcers, burning with urination, flu-like symptoms or any other sign of infection.**

You may have a low number of white blood cells that fight infection. Patients receiving Istodax can develop serious infections that sometimes lead to death.

- **Abnormal heart-beat, or feeling dizzy or faint.**

This could be due to a change in your heart-rate and/or low levels of potassium or magnesium in your blood.

- **Sudden pain in your chest or difficulty in breathing.**

This may be due to blood clots in the artery leading to your lungs.

- **Pain or swelling in your legs, especially in your lower leg or calves.**

This may be due to blood clots in the veins of your leg.

- **Heavy bleeding in the absence of injury.**

You may have a very low number of platelets, which are the blood cells that help to clot your blood.

- **Racing heart, extreme fatigue, headaches.**

You may have a very low number of red blood cells that carry oxygen.

The above list includes very serious side effects. You may need urgent medical attention or hospitalisation. Serious side effects have been reported less frequently.

Tell your doctor or pharmacist if you notice anything that is making you unwell.

Other side effects not listed above may also occur in some people.

AFTER RECEIVING ISTODAX

Storage

Your doctor or pharmacist is responsible for storing Istodax. They are also responsible for disposing of any unused Istodax correctly.

PRODUCT DESCRIPTION

What Istodax looks like

Istodax is supplied as a dual pack with one vial containing the white to off-white Istodax powder and the other vial containing a clear solvent.

Ingredients

Istodax contains romidepsin as the active ingredient. It also contains povidone (in the powder vial) and anhydrous ethanol and propylene glycol (in the solvent vial).

This medicine does not contain lactose, sucrose, gluten, tartrazine or any other azo dyes.

This is not all the information available on Istodax. If you have any more questions or are unsure about anything, ask your doctor.

Supplier

Istodax is supplied in Australia by: Celgene Pty Ltd.

Level 15, 60 City Road, Southbank, VIC 3006.

Telephone: 1800 CELGENE (1800 235 4363)

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This leaflet was updated on 06 December 2016.

Australian Registration Number: 198854.

Celgene V1.3.0