Romidepsin (Istodax®)

Pronounced: ROE-mi-DEP-sin

Classification: Histone Deacetylase Inhibitor

About Romidepsin (Istodax®)

Romidepsin belongs to a class of drugs called histone deacetylase (HDAC) inhibitors. HDACs are enzymes that control histones, which are important proteins in the expression of DNA. Romidepsin blocks HDACs so histones cannot be modulated properly. This interferes with the genetic makeup of cancer cells, leading to cell death.

How to Take Romidepsin

Romidepsin is given by intravenous (into a vein) infusion. The dose is based on your body size. How often you receive the medication will be determined by your provider.

The blood levels of this medication can be affected by certain foods and medications, so they should be avoided. These include grapefruit, grapefruit juice, ketoconazole, itraconazole, clarithromycin, voriconazole, rifampin, phenytoin, St. John’s wort, and modafinil. Be sure to tell your healthcare provider about all medications and supplements you take. If you are taking warfarin (Coumadin), you may need more frequent monitoring of your INR level.

Possible Side Effects of Romidepsin

There are a number of things you can do to manage the side effects of romidepsin. Talk to your care team about these recommendations. They can help you decide what will work best for you. These are some of the most common or important side effects:

Infection and Low White Blood Cell Count (Leukopenia or Neutropenia)

White blood cells (WBC) are important for fighting infection. While receiving treatment, your WBC count can drop, putting you at a higher risk of getting an infection. You should let your doctor or nurse know right away if you have a fever (temperature greater than 100.4°F or 38°C), sore throat or cold, shortness of breath, cough, burning with urination, or a sore that doesn’t heal.

Tips to preventing infection:

- Washing hands, both yours and your visitors, is the best way to prevent the spread of infection.
- Avoid large crowds and people who are sick (i.e.: those who have a cold, fever, or cough or live with someone with these symptoms).
- When working in your yard, wear protective clothing including long pants and gloves.
- Do not handle pet waste.
- Keep all cuts or scratches clean.
- Shower or bath daily and perform frequent mouth care.
- Do not cut cuticles or ingrown nails. You may wear nail polish, but not fake nails.
- Ask your oncology care team before scheduling dental appointments or procedures.
- Ask your oncology care team before you, or someone you live with has any vaccinations.

Low Red Blood Cell Count (Anemia)

Your red blood cells are responsible for carrying oxygen to the tissues in your body. When the red cell count is low, you may
feel tired or weak. You should let your oncology care team know if you experience any shortness of breath, difficulty breathing, or pain in your chest. If the count gets too low, you may receive a blood transfusion.

**Low Platelet Count (Thrombocytopenia)**

Platelets help your blood clot, so when the count is low you are at a higher risk of bleeding. Let your oncology care team know if you have any excess bruising or bleeding, including nose bleeds, bleeding gums, or blood in your urine or stool. If the platelet count becomes too low, you may receive a transfusion of platelets.

- Do not use a razor (an electric razor is fine).
- Avoid contact sports and activities that can result in injury or bleeding.
- Do not take aspirin (salicylic acid), non-steroidal, anti-inflammatory medications (NSAIDs) such as Motrin/Advil (ibuprofen), Aleve (naproxen), Celebrex (celecoxib), etc. as these can all increase the risk of bleeding. Please consult with your healthcare team regarding the use of these agents and all over-the-counter medications/supplements while on therapy.
- Do not floss or use toothpicks and use a soft-bristle toothbrush to brush your teeth.

**Nausea and/or Vomiting**

Talk to your oncology care team so they can prescribe medications to help you manage nausea and vomiting. In addition, dietary changes may help. Avoid things that may worsen the symptoms, such as heavy or greasy/fatty, spicy or acidic foods (lemons, tomatoes, oranges). Try saltines, or ginger ale to lessen symptoms.

Call your oncology care team if you are unable to keep fluids down for more than 12 hours or if you feel lightheaded or dizzy at any time.

**Fatigue**

Fatigue is very common during cancer treatment and is an overwhelming feeling of exhaustion that is not usually relieved by rest. While on cancer treatment, and for a period after, you may need to adjust your schedule to manage fatigue. Plan times to rest during the day and conserve energy for more important activities. Exercise can help combat fatigue; a simple daily walk with a friend can help. Talk to your healthcare team for helpful tips on dealing with this side effect.

**Decrease in Appetite or Taste Changes**

Nutrition is an important part of your care. Cancer treatment can affect your appetite and, in some cases, the side effects of treatment can make eating difficult. Ask your oncology care team about nutritional counseling services at your treatment center to help with food choices.

- Try to eat five or six small meals or snacks throughout the day, instead of 3 larger meals.
- If you are not eating enough, nutritional supplements may help.
- You may experience a metallic taste or find that food has no taste at all. You may dislike foods or beverages that you liked before receiving cancer treatment. These symptoms can last for several months or longer after treatment ends.
- Avoid any food that you think smells or tastes bad. If red meat is a problem, eat chicken, turkey, eggs, dairy products, and fish without a strong smell. Sometimes cold food has less of an odor.
- Add extra flavor to meat or fish by marinating it in sweet juices, sweet and sour sauce, or dressings. Use seasonings like basil, oregano, or rosemary to add flavor. Bacon, ham, and onion can add flavor to vegetables.

**Diarrhea**

Your oncology care team can recommend medications to relieve diarrhea. Also, try eating low-fiber, bland foods, such as white rice and boiled or baked chicken. Avoid raw fruits, vegetables, whole-grain breads, cereals, and seeds. Soluble fiber is found in some foods and absorbs fluid, which can help relieve diarrhea. Foods high in soluble fiber include applesauce, bananas (ripe), canned fruit, orange sections, boiled potatoes, white rice, products made with white flour, oatmeal, cream of rice, cream of wheat, and farina. Drink 8-10 glasses of non-alcoholic, un-caffeinated fluid a day to prevent dehydration.

**Less common, but important side effects can include:**

- **Hepatitis B Reactivation:** This medication can also cause Hepatitis B reactivation in patients who have previously had...
hepatitis. Be sure your healthcare provider is aware of any previous Hepatitis B diagnosis and treatment. You will also be tested for the Hepatitis B virus prior to beginning treatment with this medication.

- **Tumor Lysis Syndrome:** If there are a large number of tumor cells in your body prior to treatment, you are at risk for tumor lysis syndrome. This happens when the tumor cells die too quickly and their waste overwhelms the body. You may be given medication (allopurinol) and IV fluids to help prevent this. If you experience nausea, vomiting, diarrhea, or become lethargic (drowsy, sluggish), notify your oncology team right away. TLS can affect your kidney function. Your provider will monitor your kidney function with blood work. Notify your provider if you have little or no urine output.

- **Cardiac Concerns:** Tell your oncology team if you have any cardiac (heart) problems, including irregular heartbeat or a condition called QT prolongation. This medication can cause changes in the electrical activity of your heart, resulting in changes seen on an electrocardiogram (ECG or EKG). Report any feelings of rapid or abnormal heartbeat, chest pain, or shortness of breath to your healthcare team.

**Reproductive Concerns**

Exposure of an unborn child to this medication could cause birth defects, so you should not become pregnant or father a child while on this medication. Effective birth control is necessary during treatment and for one month after your last dose. Even if your menstrual cycle stops or you believe you are not producing sperm, you could still be fertile and conceive. Romidepsin can reduce the effectiveness of estrogen-containing birth control (pills, patches, IUDs) and additional effective methods of birth control should be used. You should not breastfeed while receiving this medication or for one week after your last dose.