Omacetaxine Mepesuccinate (Synribo®)

Pronounced: OH-ma-set-AX-een MEP-i-SUX-in-ate

Classification: Protein Synthesis Inhibitor

About Omacetaxine Mepesuccinate (Synribo®)

Omacetaxine mepesuccinate is a type of medication called a protein synthesis inhibitor. The exact mechanism of action is not well understood, but it does appear to work differently than other medications for CML. The medication inhibits proteins, which in turn, reduces the levels of Bcr-Abl (Philadelphia chromosome) in the body.

How to Take Omacetaxine Mepesuccinate

Omacetaxine mepesuccinate is given by a subcutaneous (SQ) injection, similar to the way insulin is given. How often you receive the medication will be determined by your provider.

Follow instructions provided by your care team on how to administer the medication. You or your caregiver should wear gloves and protective eyewear while giving the medication. If you get the medication on your skin, wash with soap and water. If you get it in your eyes, flush your eyes with water and call your healthcare provider right away. Do not eat or drink while handling this medication and always wash your hands before and after giving you the medication. Pregnant or nursing women should not prepare the dose for you. If you miss a dose, skip that dose and give the next dose at the regularly scheduled time. Do not take 2 doses to make up for a missed dose.

Storage and Handling

The medication will be pre-mixed in single-dose syringes by your healthcare team. Transport the medication as instructed by your provider. You can store vials in the refrigerator for up to 6 days or at room temperature for up to 12 hours. When stored in the refrigerator, keep away from food and drink. Keep the vials out of the reach of children and pets.

Do not reuse or recap syringes or needles. Do not throw the vials, syringes, or needles in the household trash. Dispose of all used needles and syringes in a puncture-proof disposable container with a lid. The FDA provides further information about the disposal of vials, syringes, and needles.

If the medication is spilled, use the supplies provided to clean up the spill. Do not touch the spill unless you are wearing gloves and protective eyewear. Use an absorbent pad to wipe up the spill. Wash the area with soap and water and use a paper towel to dry. Dispose of all materials in a biohazard container and report the spill to your provider.

Where do I get this medication?

Omacetaxine mepesuccinate is available through select specialty pharmacies. Your oncology team will work with your prescription drug plan to identify an in-network specialty pharmacy for the distribution of this medication and shipment directly to your home.

Insurance Information

This medication may be covered under your prescription drug plan. Patient assistance may be available to qualifying individuals without prescription drug coverage. Co-pay cards, which reduce the patient co-pay responsibility for eligible commercially (non-government sponsored) insured patients, may also be available. Your care team can help you find these
resources if they are available.

Possible Side Effects of Omacetaxine Mepesuccinate

There are a number of things you can do to manage the side effects of omacetaxine mepesuccinate. 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:

**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.

**Infection and Low White Blood Cell Count (Leukopenia or Neutropenia)**
This medication can cause life-threatening infections, with or without a decrease in white blood cell counts. 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.

**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.

**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.

**Injection Site Reactions**

Pain, redness, or swelling may occur at the injection site. This typically lasts less than 10-15 minutes. Rotating the site of the injections is helpful to reduce injection site discomfort.

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

- **GI Bleed & Stroke**: This medication can cause bleeding in the GI tract and stroke; particularly in patients with low platelet counts. Symptoms of gastrointestinal bleeding include unexpected bleeding, blood in the stool or black stools, coughing up blood, vomiting blood, vomit that looks like coffee grounds, fever, severe pain in the abdomen, or new abdominal swelling. Signs of a stroke include numbness or weakness on one side of the body, trouble talking, confusion, or mental status changes. If you experience any of these, contact your healthcare provider immediately or go to the emergency room.

- **High Blood Sugar**: This medication can cause elevated blood sugar levels in patients with and without diabetes. Your healthcare team will monitor your blood sugar. If you develop increased thirst, urination or hunger, blurry vision, headaches or your breath smells like fruit, notify your healthcare team. Diabetics should monitor their blood sugar closely and report elevations to the 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 six months after treatment for women and three months after treatment for men. Even if your menstrual cycle stops or you believe you are not producing sperm, you could still be fertile and conceive. You should not breastfeed while receiving this medication.

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