

Omacetaxine mepesuccinate (Synribo)

About This Medicine

Omacetaxine is used to treat cancer. It is given as an injection under the skin (subcutaneously).

Possible Side Effects

- Bone marrow suppression. This is a decrease in the number of white blood cells, red blood cells, and platelets. This may raise your risk of infection, make you tired and weak, and raise your risk of bleeding.
- Nausea
- Diarrhea (loose bowel movements)
- Fever
- Infection
- Tiredness and weakness
- Injection site reaction you may get a rash, swelling or bruising or your skin may get red, warm, itchy or painful at the site of your injection

Note: Each of the side effects above was reported in 20% or greater of patients treated with omacetaxine. All possible side effects are not included. Your side effects may be different depending on your cancer diagnosis, condition, or if you are receiving other medicines in combination. Please discuss any concerns or questions with your medical team.

Warnings and Precautions

- Severe bone marrow suppression, which may be life-threatening.
- · Blood sugar levels may change
- Abnormal bleeding, which may be life-threatening. Symptoms may include coughing up blood, throwing up blood (may look like coffee grounds), red or black tarry bowel movements, abnormally heavy menstrual flow, nosebleeds or any other unusual bleeding.

Note: Some of the side effects above are very rare. If you have concerns and/or questions, please discuss them with your medical team.

Important Information



- This medicine may impair your ability to drive or use machinery. Use caution and talk to your doctor and/or nurse about any precautions you may need to take.
- If you plan to have any dental and/or surgical procedures, tell the doctor that you are on omacetaxine mepesuccinate.

How to Take Your Medicine

- Talk to your doctor, nurse and/or pharmacist for proper preparation, dosing and administration if you are self-injecting.
- Missed dose: If you miss a dose, take your next scheduled dose at the next scheduled time, and contact your physician. Do not take 2 doses at the same time and do not double up on the next dose.
- **Handling:** Wash your hands with soap and water before and after handling your medicine, you and your caretakers should not handle your medicine with bare hands and should wear latex gloves, and protective eyeglasses and/or a face shield when handling and while giving your injection.
- Do not inject your medicine around children or pregnant women.
- Do not eat or drink while handling your medicine.
- If you or your caregiver get any medicine on your skin, you should wash the area of the skin well
 with soap and water right away and call your doctor right away. If any of the medicine splashes in
 your eyes, wash your eyes with flowing water and call your doctor right away.
- Any medicine spills should be cleaned up right away. Call your nurse, for further instructions and for the necessary precautions to take.
- Cytotoxic medicines leave the body through urine and stool, but they can also be present in other body fluids such as blood, vomit, semen, and vaginal fluids. Take precautions to prevent others from coming in contact with your medicine or your body fluids. Follow safety precautions during your treatment and for as long as directed by your health care provider after your treatment. If you take a cytotoxic pill each day, follow these precautions every day.
- **Storage:** When stored in a refrigerator, 36°F to 46°F (2°C to 8°C), use this medicine within 6 days from when it was mixed. When stored at room temperature, 68°F to 77°F (20°C to 25°C), use this medicine within 12 hours from when it was mixed.
- **Disposal:** Discuss with your nurse or your doctor how to dispose of unused medicine/needles.

Treating Side Effects

- Manage tiredness by pacing your activities for the day.
- Be sure to include periods of rest between energy-draining activities.
- To decrease the risk infection, wash your hands regularly.
- Avoid close contact with people who have a cold, the flu, or other infections.
- Take your temperature as your doctor or nurse tells you, and whenever you feel like you may have a fever.
- To help decrease the risk of bleeding, use a soft toothbrush. Check with your nurse before using dental floss.
- Be very careful when using knives or tools.
- Use an electric shaver instead of a razor.



- Drink enough fluids to keep your urine pale yellow.
- If you throw up or have diarrhea, you should drink more fluids so that you do not become dehydrated (lack of water in the body from losing too much fluid). Eat low-fiber foods that are high in protein and calories and avoid foods that can irritate your digestive tracts or lead to cramping.
- Ask your nurse or doctor about medicine that can lessen or stop your diarrhea or constipation.
- To help with nausea and vomiting, eat small, frequent meals instead of three large meals a day. Choose foods and drinks that are at room temperature. Ask your nurse or doctor about other helpful tips and medicine that is available to help stop or lessen these symptoms.
- If you are not able to move your bowels, check with your doctor or nurse before you use enemas, laxatives, or suppositories.
- If you have diabetes, keep good control of your blood sugar level. Tell your nurse or your doctor if your glucose levels are higher or lower than normal.
- While you are getting this medicine, please tell your nurse right away if you get a rash, swelling or bruising or your skin gets red, warm, itchy or painful at the site of your injection.
- Keeping your pain under control is important to your well-being. Please tell your doctor or nurse if you are experiencing pain.
- If you get a rash do not put anything on it unless your doctor or nurse says you may. Keep the area around the rash clean and dry. Ask your doctor for medicine if your rash bothers you.
- To help with hair loss, wash with a mild shampoo and avoid washing your hair every day. Avoid coloring your hair.
- Avoid rubbing your scalp, pat your hair or scalp dry.
- Limit your use of hair spray, electric curlers, blow dryers, and curling irons.
- If you are interested in getting a wig, talk to your nurse and they can help you get in touch with programs in your local area.

Food and Medicine Interactions

- There are no known interactions of omacetaxine with food.
- This medicine may interact with other medicines. Tell your doctor and pharmacist about all the prescription and over-the-counter medicines and dietary supplements (vitamins, minerals, herbs, and others) that you are taking at this time. Also, check with your doctor or pharmacist before starting any new prescription or over-the-counter medicines, or dietary supplements to make sure that there are no interactions.

When to Call the Doctor

Call your doctor or nurse if you have any of these symptoms and/or any new or unusual symptoms:

- Fever of 100.4° F (38° C) or higher
- Chills
- Tiredness and/or weakness that interferes with your daily activities
- Feeling dizzy or lightheaded



- Signs of abnormal bleeding such as coughing up blood, throwing up blood (may look like coffee grounds), easy bleeding or bruising, red or black tarry bowel movements, abnormally heavy menstrual flow, nosebleeds, or any other unusual bleeding
- Nausea that stops you from eating or drinking and/or is not relieved by prescribed medicines
- Throwing up more than 3 times a day
- Diarrhea, 4 times in one day or diarrhea with lack of strength or a feeling of being dizzy
- No bowel movement in 3 days or when you feel uncomfortable
- Pain in your abdomen that does not go away
- Unusual thirst, passing urine often, headache, sweating, shakiness, irritability, rapid and deep breathing
- Abnormal blood sugar
- Signs of infection: fever or chills, cough, trouble breathing, severe pain in your abdomen, difficulty urinating, burning or pain when you pass urine, redness and/or swelling of the skin
- New rash and/or itching or a rash that is not relieved by prescribed medicines
- If you think you may be pregnant or may have impregnated your partner

Reproduction Warnings

- Pregnancy warning: This medicine can have harmful effects on the unborn baby. Women of
 child-bearing potential should use effective methods of birth control during your cancer treatment
 and for 6 months after stopping treatment. Men with female partners of childbearing potential
 should use effective methods of birth control during your cancer treatment and for 3 months after
 stopping treatment. Let your doctor know right away if you think you may be pregnant or may have
 impregnated your partner.
- **Breastfeeding warning**: Women should not breastfeed during treatment and for 2 weeks after stopping treatment because this medicine could enter the breast milk and cause harm to a breastfeeding baby.
- **Fertility warning:** In men, this medicine may affect your ability to have children in the future. Talk with your doctor or nurse if you plan to have children. Ask for information on sperm banking.

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