

Tisotumab vedotin-tftv (Tivdak)

About This Medicine

Tisotumab vedotin-tftv is used to treat cancer. It is given in the vein (IV).

Possible Side Effects

- Decrease in the number of white blood cells and red blood cells. This may raise your risk of infection and make you tired and weak.
- Eye irritation, dry eye, vision changes, and ulcers on your cornea. You may have red, painful, teary, dry, or crusting eyes.
- Nausea
- Diarrhea (loose bowel movements)
- Tiredness
- Abnormal bleeding – symptoms may be coughing up blood, throwing up blood (may look like coffee grounds), red or black tarry bowel movements, abnormally heavy menstrual flow, or any other unusual bleeding.
- Nosebleed
- Effects on the nerves are called peripheral neuropathy. You may feel numbness, tingling, or pain in your hands and feet. It may be hard for you to button your clothes, open jars, or walk as usual. The effect on the nerves may get worse with more doses of the medicine. These effects get better in some people after the medicine is stopped but it does not get better in all people.
- Changes in your kidney function
- Changes in your blood clotting function
- Rash
- Hair loss. Hair loss is often temporary, although with certain medicine, hair loss can sometimes be permanent. Hair loss may happen suddenly or gradually. If you lose hair, you may lose it from your head, face, armpits, pubic area, chest, and/or legs. You may also notice your hair getting thin.

Note: Each of the side effects above was reported in 25% or greater of patients treated with tisotumab vedotin-tftv. 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



- Blurred vision or other changes in eyesight, severe dry eye, inflammation of the eyelids, and/or ulcers on your cornea. Some of these changes can be severe and cause loss of vision.
- Severe peripheral neuropathy and muscle weakness
- Severe abnormal bleeding
- Inflammation (swelling) of the lungs, which can be life-threatening. You may have a dry cough or trouble breathing.
- Severe allergic skin reaction, which may be life-threatening. You may develop blisters on your skin that are filled with fluid or a severe red rash all over your body that may be painful.

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

- You should use steroid and vasoconstrictor eye drops before each infusion. Bring the eye drops with you for your treatments. Cooling eye pads may be used during your infusion.
- You should continue the steroid eye drops as prescribed by your provider for 72 hours after each treatment.
- You should use artificial tears, hydrating or lubricating eye gels to help prevent or treat dry eyes during treatment and for 30 days after treatment. Ask your nurse or doctor for more information about which product they recommend for you.
- It is recommended to avoid wearing contact lenses during treatment.
- 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.

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 of 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.
- 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 diarrhea.
- 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 have a nosebleed, sit with your head tipped slightly forward. Apply pressure by lightly pinching the bridge of your nose between your thumb and forefinger. Call your doctor if you feel dizzy or faint or if the bleeding doesn't stop after 10 to 15 minutes.
- If you have numbness and tingling in your hands and feet, be careful when cooking, walking, and handling sharp objects and hot liquids.
- 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

- This medicine may interact with grapefruit and grapefruit juice. Talk to your doctor as this could make side effects worse.
- Check with your doctor or pharmacist about all other prescription medicines and over-the-counter medicines and dietary supplements (vitamins, minerals, herbs, and others) you are taking before starting this medicine as there are known medicine interactions with tisotumab vedotin-tftv. 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
- Blurred vision or other changes in eyesight
- Red, painful, teary, or crusty eye
- Dry and/or itchy eye
- Pain in your chest
- Dry cough
- Trouble breathing
- Painful sores in your mouth, nose, throat and/or genital area
- 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



- 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, or any other unusual bleeding
- Nosebleed that doesn't stop bleeding after 10 -15 minutes
- Decreased or very dark urine
- Numbness, tingling, or pain in your hands and feet
- Flu-like symptoms: fever, headache, muscle and joint aches, and tiredness
- A 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 childbearing potential should use effective methods of birth control during your cancer treatment and for 2 months after stopping treatment. Men with female partners of childbearing potential should use effective methods of birth control during your cancer treatment and for 4 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 breast feed during treatment and for 3 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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