

## Tisotumab vedotin-tftv (Tivdak)

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### About This Medicine

TISOTUMAB VEDOTIN (tye SOT ue mab ve DOE tin) treats cervical cancer. It works by blocking a protein that causes cancer cells to grow and multiply. This helps to slow or stop the spread of cancer cells. It is given in the vein (IV).

This medicine may be used for other purposes; ask your care team if you have questions.

### Possible Side Effects

- Decrease in red blood cells. This may make you feel more tired.
- Eye irritation, dry eye, vision changes, and ulcers on your cornea. You may have red, painful, teary, dry, or crusty eyes.
- Nausea
- 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 liver function
- 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 people 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 care 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 care team.

## Important Information

- You should use steroid and vasoconstrictor eye drops before each infusion and continue the steroid eye drops as prescribed by your provider for 72 hours after each treatment. Bring the eye drops with you for your treatments. Cooling eye pads may be used during your infusion.
- 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 care team for more information about which product they recommend for you.
- Your vision will be tested before and during use of this medicine. Do not wear contact lenses during treatment unless you are told to use them by your eye doctor.
- This medicine may be present in the urine, stool and 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 care team after your treatment. If you take a 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.
- Get regular exercise, with your care team's approval. If you feel too tired to exercise vigorously, try taking a short walk.
- Drink enough fluids to keep your urine pale yellow.
- If you throw up, 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.
- 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 care team 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 care team 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 care team says you may. Keep the area around the rash clean and dry. Ask your care team 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 care team 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 care team as this could make side effects worse.
- Check with your care team 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 care team before starting any new prescription or over-the-counter medicines, or dietary supplements to make sure that there are no interactions.

## When to Call Your Care Team

Call your care team 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
- 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
- Numbness, tingling, or pain in your hands and feet

- Signs of possible liver problems: dark urine, pale bowel movements, pain in your abdomen, feeling very tired and weak, unusual itching, or yellowing of the eyes or skin
- Flu-like symptoms: fever, headache, muscle and joint aches, and tiredness
- Swollen lymph nodes in your neck and/or armpits
- A new rash and/or itching or a rash that is not relieved by prescribed medicines

## Reproduction Warnings

- **Pregnancy warning:** This medicine can cause serious birth defects. If you can become pregnant, use birth control while taking this medicine and for 2 months after the last dose. If you can get your partner pregnant, use birth control while taking this medicine and for 4 months after the last dose. Tell your care team right away if you think you might be pregnant or think your partner might be pregnant.
- **Breastfeeding warning:** Do not breastfeed while taking this medicine and for 3 weeks after the last dose.
- **Fertility warning:** This medicine may affect your ability to have children in the future. If you plan to have children, talk with your care team.

Revised July 2025

