Tisotumab Vedotin-tftv (Tivdak™)

**Pronounced:** tye SOT ue mab ve DOE tin

**Classification:** monoclonal antibody; antibody drug conjugate

### About Tisotumab Vedotin-tftv (Tivdak™)

Monoclonal antibodies are created in a lab to attach to targets, in this case a protein called tissue factor (TF), found on some types of cancer cells. The antibody “calls” the immune system to attack the cell it is attached to, resulting in the immune system killing the cell.

Tisotumab vedotin-tftv is a monoclonal antibody attached to a chemotherapy agent called monomethyl auristatin E (MMAE), which is a microtubule inhibitor.

This medication targets a protein called tissue factor (TF). TF is found in normal cells and helps with the clotting process. Some cancer cells have too much TF on their surface, which can lead to tumor growth and spread (metastasis). Tisotumab vedotin-tftv attaches itself to the TF receptors on cancer cells and pushes the chemotherapy into the cell.

### How to Take Tisotumab Vedotin-tftv

Tisotumab vedotin-tftv is given by intravenous (IV, into a vein) infusion. The dose you receive is based on your body size and will be determined by your oncology team.

### Possible Side Effects

There are a number of things you can do to manage the side effects of Tisotumab vedotin-tftv. 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:

**Ocular Toxicity (Eye problems)**

Tisotumab vedotin-tftv can cause changes to your eyes that can lead to loss of vision, corneal ulceration, conjunctivitis, dry eye, and inflammation of the eyelids. You will have an eye exam before starting treatment, before every dose you receive, and as indicated throughout treatment. Before your infusion with tisotumab vedotin-tftv, you will be given eye drops that have a corticosteroid in them. Your care team may place cold packs on your eyes during the infusion. You will be taught how to give yourself the eye drops after your infusion for up to 3 days. You may be asked to also use lubricating eye drops after your last dose is given. Call your care team right away if you have any changes in your vision or pain in your eyes.

**Hemorrhage (Bleeding)**

Patients may have minor bleeding, such as a nosebleed, while on this medication. Serious bleeding has also occurred, including blood in the urine and vaginal bleeding. These events are uncommon, though if they occur, tisotumab vedotin-tftv should be discontinued. While a nosebleed may not seem like much of a concern, you should call your healthcare team right away if you have bleeding of any sort.

**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.
**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.

**Infection and Low White Blood Cell Count (Leukopenia/Neutropenia/Lymphocytopenia)**

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.

**Peripheral Neuropathy (Numbness or Tingling in the Hands and/or Feet)**

Peripheral neuropathy is a toxicity that affects the nerves. It causes numbness or a tingling feeling in the hands and/or feet, often in the pattern of a stocking or glove. This can get progressively worse with additional doses of the medication. In some people, the symptoms slowly resolve after the medication is stopped, but for some, it never goes away completely. You should let the oncology care team know if you experience numbness or tingling in the hands and/or feet, as they may need to adjust the doses of your medication.

**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.

**Loss or Thinning of Scalp and Body Hair (Alopecia)**

Your hair may become thin, brittle, or may fall out. This typically begins two to three weeks after treatment starts. This hair loss can be all body hair, including pubic, underarm, legs/arms, eyelashes, and nose hairs. The use of scarves, wigs, hats and hairpieces may help. Hair generally starts to regrow soon after treatment is completed. Remember your hair helps keep you warm in cold weather, so a hat is particularly important in cold weather or to protect you from the sun.

**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.
Rash
Some patients may develop a rash, scaly skin, or red itchy bumps. Use an alcohol-free moisturizer on your skin and lips; avoid moisturizers with perfumes or scents. Your oncology care team can recommend a topical medication if itching is bothersome. If your skin does crack or bleed, be sure to keep the area clean to avoid infection. Be sure to notify your oncology care team of any rash that develops, as this can be a reaction. They can give you more tips on caring for your skin.

Kidney Problems
This medication can cause kidney problems, including an increased creatinine level, which your oncology care team may monitor for using blood tests. Notify your healthcare provider if you notice decreased urine output, blood in the urine, swelling in the ankles, or loss of appetite.

Constipation
There are several things you can do to prevent or relieve constipation. Include fiber in your diet (fruits and vegetables), drink 8-10 glasses of non-alcoholic fluids a day, and keep active. A stool softener once or twice a day may prevent constipation. If you do not have a bowel movement for 2-3 days, you should contact your healthcare team for suggestions to relieve the constipation.

Abdominal (Belly) Pain
Your care team can recommend ways to improve pain. If you have abdominal pain with changes in your bowel movements, call your provider.

Muscle or Joint Pain/Aches
Your healthcare provider can recommend medications and other strategies to help relieve pain.

Less common but important side effects can include:

- **Pneumonitis**: Patients can develop an inflammation of the lungs (called pneumonitis) while taking this medication. Notify your oncology care team right away if you develop any new or worsening symptoms, including shortness of breath, trouble breathing, cough, or fever.

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 at least 2 months after treatment for women and for 4 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 or for 3 weeks after your last dose.

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