Enfortumab Vedotin-ejfv (PADCEV™)

Pronounced: en-FORT-ue-mab ve-DOE-tin ejfv

Classification: monoclonal antibody

About Enfortumab Vedotin-ejfv (PADCEV™)

Monoclonal antibodies are created in a lab to attach to the targets, in this case Nectin 4, found on specific 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. These antibodies can work in different ways, and this medication works as a microtubule inhibitor. These antibodies can work in different ways, including stimulating the immune system to kill the cell, blocking cell growth or other functions necessary for cell growth.

Enfortumab Vedotin-ejfv is a monoclonal antibody attached to a chemotherapy agent called monomethyl auristatin E (MMAE) which is a microtubule inhibitor. This medication targets Nectin-4 positive urothelial cancer cells. Enfortumab Vedotin-ejfv attaches itself to the Nectin-4 receptors on cancer cells and pushes the chemotherapy into the cell.

How to Take Enfortumab Vedotin-ejfv

Enfortumab vedotin-ejfv is given as an intravenous infusion. The dose is based on your weight. How often you receive the medication will be determined by your provider.

Even when carefully and correctly administered by trained personnel, this drug may cause a feeling of burning and pain. There is a risk that this drug may leak out of the vein at the injection site, resulting in tissue damage. If the area of injection becomes red, swollen, or painful at any time during or after the injection, notify your doctor or nurse immediately. Do not apply anything to the site unless instructed by your doctor or nurse.

The blood levels of this medication can be affected by certain foods and medications, so they should be avoided. These include grapefruit, grapefruit juice, Apalutamide, Atazanavir, Carbamazepine, Clarithromycin, Cobicistat, Darunavir, Dasabuvir, Enzalutamide, Fosphenytoin, Idelalisib, Indinavir, Itraconazole, Ketoconazole, Lopinavir, Lumacaftor, Mifepristone, Mitotane, Nelfinavir, Ombitasvir, Paritaprevir, Phenobarbital, Phenytoin, Posaconazole, Primidone, Ritonavir, Saquinavir, Telithromycin, and Voriconazole, among others. Be sure to tell your healthcare provider about all medications and supplements you take.

Possible Side Effects

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

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.

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.

**Skin Changes**

Some patients may develop a rash, dry skin or itching. In some cases, you can develop a very serious skin reaction in which your skin can blister or peel. These reactions are called either Steven Johnsons syndrome or toxic epidermal necrolysis. You should contact your care team right away if you have any changes to your skin. They will be able to tell you how to best care for your skin depending on your reaction.

**Decrease in Appetite or Taste Changes**

Nutrition is an important part of your care. Cancer treatment can affect your appetite and, in some cases, the side effects of treatment can make eating difficult. Ask your oncology care team about nutritional counseling services at your treatment center to help with food choices.

- Try to eat five or six small meals or snacks throughout the day, instead of 3 larger meals.
- If you are not eating enough, nutritional supplements may help.
- You may experience a metallic taste or find that food has no taste at all. You may dislike foods or beverages that you liked before receiving cancer treatment. These symptoms can last for several months or longer after treatment ends.
- Avoid any food that you think smells or tastes bad. If red meat is a problem, eat chicken, turkey, eggs, dairy products, and fish without a strong smell. Sometimes cold food has less of an odor.
- Add extra flavor to meat or fish by marinating it in sweet juices, sweet and sour sauce or dressings. Use seasonings like basil, oregano, or rosemary to add flavor. Bacon, ham, and onion can add flavor to vegetables.

**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.

**Eye Problems**

This medication can cause changes to your sight including blurry vision and dryness. You may be instructed to use eye drops that work as tear substitutes. Talk to your provider if you are having any changes in your vision.

**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.

**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 on non-alcoholic, un-caffeinated fluid a day to prevent dehydration.

**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.

**Low White Blood Cell Count (Leukopenia or Neutropenia)**

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.

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

- **High Blood Sugar:** This medication can cause elevated blood sugar levels in patients with and without diabetes. Your oncology care 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.
- **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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