

Talimogene Laherparepvec (Imlygic™, T-VEC)

Pronounced: tal-IM-oh-jeen la-her-pa-REP-vek

Classification: genetically modified oncolytic viral therapy

About Talimogene Laherparepvec (Imlygic™, T-VEC)

Talimogene Laherparepvec is a genetically modified virus. It is a weakened version of the Herpes Simplex Virus Type 1, which can cause cold sores. It replicates within a tumor and produces a protein called GM-CSF that starts an immune response. This causes the lysis (breakdown) of cancer cells.

How to Take Talimogene Laherparepvec

Talimogene Laherparepvec is injected directly into a tumor that is visible or palpable (able to be felt). It can also be injected into a tumor that is detectable with ultrasound guidance. The dose is dependent upon the number of tumors being treated and the size of those tumors.

This medication should not be used in patients who are pregnant or have a compromised immune system from HIV, AIDS, blood or bone marrow cancer, autoimmune disease, or who are being treated with steroids. The effectiveness of talimogene laherparepvec can be affected by anti-viral medications, such as acyclovir.

How to Administer Talimogene Laherparepvec

The area to be injected will be cleaned with an alcohol swab and given time to dry. The site may be treated with a local anesthetic (numbing medication). A needle with the medication will be inserted into the tumor, and the medication injected. The needle may be moved around to inject the full dose into different parts of the tumor. This will be repeated for each tumor being treated. The needle will be removed slowly and pressure will be held on the injection site with sterile gauze for at least 30 seconds. The area will be cleaned with alcohol and covered with a sterile dressing.

The site should remain covered with an airtight and watertight dressing for at least the first week after each treatment, or longer if the site is weeping or oozing. Avoid touching or scratching the injection site. Wash your hands well with soap and water before and after any contact with the injection site or dressings. All dressings and cleaning materials should be disposed of in a sealed plastic bag placed in with your household trash.

Accidental exposure to talimogene laherparepvec can lead to herpes infection. Caregivers should wear gloves when assisting with changing dressings or coming in contact with fluid from the tumor site. If they come into contact with the soiled dressings or drainage, they should clean the area well with soap and water. Immunocompromised persons and pregnant women should not come in contact with the medication or any soiled materials.

Possible Side Effects of Talimogene Laherparepvec

There are a number of things you can do to manage the side effects of talimogene laherparepvec. 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:

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.

Flu-Like Symptoms

You may experience fever, chills, aches, and pains. Your doctor or nurse can recommend medication and other strategies to relieve these symptoms. This most often occurs during the first 3 months of treatment.

Injection Site Complications and Pain

The injection site should be kept clean and covered with an airtight and watertight dressing for at least 1 week after the injection. If the dressing becomes saturated, the area should be cleaned and a new dressing applied. The injection site should be closely monitored for changes in color, warmth, pain, and leaking of excess fluid or pus. Notify your provider of any of these symptoms as they could be signs of infection.

Herpes Infection

Because this medication contains the herpes virus, it can cause a herpes infection. Symptoms of a herpes infection include:

- Pain, burning, or tingling in a blister around the mouth, genitals, fingers, or ears.
- Eye pain, sensitivity, discharge from the eyes, and blurry vision.
- · Weakness in the arms and legs.
- Extreme fatigue and drowsiness.
- · Mental confusion.

If you, or anyone in close contact with you, are experiencing any of these symptoms, it is important to notify your health care provider to be evaluated.

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.

Less common, but important side effects can include:

- *Plasmacytoma:* In clinical trials, the development of plasmacytoma in patients with co-existing multiple myeloma has occurred. Be sure your healthcare team is aware if you have multiple myeloma, even if it is smoldering multiple myeloma.
- Obstructive Airway Disorder: The medication can cause breathing and airway problems if injected close to major airways.

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. Even if your menstrual cycle stops or you believe you are not producing sperm, you could still be fertile and conceive. You should consult with your healthcare team before breastfeeding while receiving this medication.

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