

Medication Guide

IMLYGIC® (imm-LY-jik) (talimogene laherparepvec)

Read the Medication Guide before you start treatment with IMLYGIC and before each IMLYGIC treatment. There may be new information. This Medication Guide does not tell you everything about IMLYGIC. Talk with your healthcare provider if you have any questions about treatment with IMLYGIC.

What is IMLYGIC?

IMLYGIC is a prescription medicine used to treat a type of cancer called melanoma when it is on your skin or in your lymph glands. IMLYGIC is a weakened form of Herpes Simplex Virus Type 1, which is commonly called the cold sore virus. Your healthcare provider will inject IMLYGIC directly into your tumor(s).

IMLYGIC may not help you live longer and may not shrink cancer in your organs (for example, lung or liver).

Who should not get IMLYGIC?

You should not get IMLYGIC if you are pregnant or have a weakened immune system (for example, an immune deficiency, blood or bone marrow cancer, steroid use, or HIV/AIDS).

What should I tell my healthcare provider before I get IMLYGIC?

Before getting IMLYGIC, tell your healthcare provider if you:

- Are taking steroids or other medicines that suppress your immune system.
- Are taking antiviral medicines to treat or prevent herpes, such as acyclovir.
- Have or ever had medical conditions such as:
 - HIV infection or AIDS.
 - Blood or bone marrow cancer.
 - Autoimmune disease.
 - Other medical conditions that can weaken your immune system.
- Have close contact with someone who has a weakened immune system or is pregnant.
- Are pregnant or plan to become pregnant.
 - IMLYGIC may harm your unborn baby.
 - You should not become pregnant during treatment with IMLYGIC.
 - Talk to your healthcare provider about effective birth control methods.
- Are breastfeeding or plan to breastfeed.

Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements. IMLYGIC may affect the way other medicines work and other medicines may affect how IMLYGIC works.

How is IMLYGIC given?

Your healthcare provider will inject IMLYGIC directly into your tumor(s) with a needle and syringe. You will get a second treatment 3 weeks after the first treatment. After that, you will get treatments every 2 weeks for as long as you have tumor(s). You can get treated for 6 months or longer.

Your healthcare provider will decide which tumor(s) to inject and may not inject every one.

It is important to care for the treatment sites properly so that IMLYGIC does not spread to other people. Your healthcare provider will show you how to do this.

What should I avoid while getting IMLYGIC?

IMLYGIC virus can spread to other areas of your body or to your close contacts (household members, caregivers, sex partners, or persons sharing the same bed).

Do the following to avoid spreading IMLYGIC to other areas of your body or to your close contacts:

- Avoid direct contact between your treatment sites, dressings, or body fluids and close contacts (for example, use condoms when engaging in sexual activity, avoid kissing close contacts if either has an open mouth sore).
- Wear gloves while putting on or changing your dressings.
- Keep treatment sites covered with airtight and watertight dressings for at least 1 week after each treatment (or longer if the treatment site is weeping or oozing).
- If the dressing comes loose or falls off, replace it right away with a clean dressing.
- Place all used dressings and cleaning materials in a sealed plastic bag and throw them away in the garbage.
- Do not touch or scratch the treatment sites.

What are possible side effects of IMLYGIC?

The most common side effects of IMLYGIC include:

- Tiredness

- Chills
- Fever
- Nausea
- Flu-like symptoms
- Pain at treatment site

Tell your doctor right away if you get any of the signs and symptoms of herpes infection, including but not limited to:

- Pain, burning, tingling, or blister formation around the mouth, genitals, or any part of the body, near or far from the injection site
- Eye pain, light sensitivity, discharge from the eyes, or blurry vision
- Weakness in arms or legs
- Extreme drowsiness (feeling sleepy)
- Mental confusion

If you think you have a herpes infection, inform your healthcare provider. Life threatening-herpes infection and herpes infection spreading to any part of the body far from the injection site (disseminated herpetic infection) may occur in patients treated with IMLYGIC. If you have any new or worsening symptoms, call your healthcare provider right away. You or your healthcare provider should call Amgen at 1-855-IMLYGIC (1-855-465-9442) for follow-up testing if needed.

These are not all the possible side effects of IMLYGIC. Your healthcare provider can give you more detailed information. Tell your healthcare provider if you have any side effects that bother you or that do not go away. You may report side effects to FDA at 1-800-FDA-1088.

What are the ingredients in IMLYGIC?

Active ingredient: talimogene laherparepvec

Inactive ingredients: di-sodium hydrogen phosphate dihydrate, sodium dihydrogen phosphate dihydrate, sodium chloride, myo-inositol, sorbitol, and water for injection

General information about the safe and effective use of IMLYGIC

This Medication Guide summarizes the most important information about IMLYGIC. Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. If you would like more information, talk with your healthcare provider. You can ask your healthcare provider for information about IMLYGIC that was written for healthcare professionals.

This Medication Guide has been approved by the U.S. Food and Drug Administration.



IMLYGIC® (talimogene laherparepvec)

Manufactured by:

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Patent: <http://pat.amgen.com/Imlygic/>

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