

Imlygic™

(imm LY jik)

talimogene laherparepvec (tal im' oh jeen la her" pa rep' vek)

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about Imlygic. It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you using Imlygic against the benefits they expect it will have for you.

If you have any concerns about using this medicine, ask your doctor, nurse or pharmacist.

Keep this leaflet.

You may need to read it again.

What Imlygic is used for

Imlygic is used to treat a type of skin cancer called melanoma that has spread in the skin and/or to the lymph nodes.

Imlygic contains a weakened form of herpes simplex virus type-1 (HSV-1), which is commonly called the cold sore virus. The virus has been altered to be able to make GM-CSF (Granulocyte-Macrophage Colony-Stimulating Factor), a protein which helps your body's immune system recognise and destroy tumours. When Imlygic is injected into tumours it destroys the melanoma.

Imlygic also helps your immune system to destroy melanoma throughout your body.

Ask your doctor if you have any questions about why this medicine has been prescribed for you.

Your doctor may have prescribed it for another reason.

This medicine is available only with a doctor's prescription.

Before you are given Imlygic

When you must not be given it

Do not have Imlygic if you have an allergy to:

- any medicine containing talimogene laherparepvec
- any of the ingredients listed at the end of this leaflet.

Some of the symptoms of an allergic reaction may include:

- shortness of breath, wheezing or difficulty breathing
- swelling of the face, lips, tongue or other parts of the body
- rash, itching or hives on the skin .

Do not have this medicine if you have a:

- severely lowered immunity

Do not have Imlygic after the expiry date printed on the pack.

Do not have Imlygic if the packaging is torn or shows signs of tampering.

If you are not sure whether you should have Imlygic, talk to your doctor.

Before you are given it

Tell your doctor if you have allergies to any other medicines, foods, preservatives or dyes.

Tell your doctor if you have or have had any of the following medical conditions:

- lowered immunity due to diseases including HIV/AIDS, blood or bone marrow cancer
- lowered immunity due to treatment with medicines such as steroids or other medicines that lower your immune system
- autoimmune disease (a condition where the body attacks itself)
- multiple myeloma (cancer of blood cells).
- if you have never had herpes infections before

Tell your doctor if you are pregnant or plan to become pregnant.

Imlygic may affect your developing baby. If it is necessary for you to have Imlygic your doctor will discuss the risks and benefits of having it during pregnancy.

Females who are able to become pregnant should use suitable birth control (contraception) methods during treatment with Imlygic.

Talk to your doctor about birth control methods (contraception) that may be right for you.

Tell your doctor if you are breast-feeding or plan to breast feed.

It is not known if Imlygic passes into breast milk. You and your doctor should decide if you should take Imlygic or breast feed. You should not do both.

If you have not told your doctor about any of the above, tell him/her before you use Imlygic.

Taking other medicines

Tell your doctor or pharmacist if you are taking any other medicines, including any that you get without a prescription from your pharmacy, supermarket or health food shop.

Tell your doctor if you are taking:

- anti-viral medicines to treat or prevent herpes, such as Famvir, Valtrex or Zovirax

These medicines may be affected by Imlygic, or may affect how well it works. You may need to use different amounts of your medicines, or take different medicines.

Your doctor or pharmacist has more information on medicines to be careful with or avoid while taking Imlygic.

How Imlygic is given

Imlygic is given as an injection into your tumour cells.

Your doctor will decide which tumours to inject and may not inject every tumour.

Your existing tumour(s) may increase in size and new tumour(s) could appear while you are being treated with Imlygic.

Your second injection of Imlygic is given 3 weeks after the first injection. Then Imlygic injections are every 2 weeks for as long as you have tumour(s).

Follow all directions given to you by your doctor, nurse or pharmacist carefully.

They may differ from the information contained in this leaflet.

If you do not understand the instructions, ask your doctor or pharmacist for help.

How long to use it

You can expect to be treated with this medicine for 6 months or longer.

If you miss a dose

If you miss a dose, talk to your doctor and arrange another visit as soon as possible.

While you are using Imlygic

Things you must do

Tell any other doctors, nurses dentists, and pharmacists who treat you that you are taking this medicine.

If you become pregnant while taking this medicine, tell your doctor immediately.

Keep all of your doctor's appointments so that your progress can be checked.

Avoid direct contact of injection sites or body fluids (blood, urine, saliva) with close contacts.

Close contacts include household members, caregivers, sex partners, or someone you share a bed with:

- use latex condoms when engaging in sexual activity
- avoid kissing close contacts if either of you has an open mouth sore while you are being treated and until 30 days after your last dose.

Your close contacts could be accidentally exposed to Imlygic, if they have direct contact with your body fluids or injection sites.

Tell your doctor if you have any close contact who has a lowered immune system or is pregnant.

Your doctor may have special instructions for them.

Care for your injection sites properly:

- avoid touching or scratching the injection sites
- keep injection sites covered at all times with watertight dressings. If the dressing comes loose or falls off, replace it with a clean dressing
- place all used dressings and cleaning materials in a sealed

plastic bag and throw them away in your household waste.

- keep used dressings and cleaning materials away from infants less than 3 months old.

Tell your close contacts to:

- avoid direct contact with your body fluids or injection sites
- cover any exposed wounds and wear gloves while changing your dressing
- clean any area with soap and water and/or a disinfectant if accidentally exposed to Imlygic, body fluids or injections sites
- contact their doctor immediately if they develop symptoms of herpes infection:
 - pain, burning or tingling, in a blister around the mouth or genitals, or on the fingers or ears
 - eye pain, light sensitivity, discharge from the eyes, redness of eye, watery or blurry vision
 - flu-like illness (fever, chills, tiredness or headache)
 - weakness in arms or legs
- other rare symptoms include mental confusion, memory loss and seizures.

Close contacts that have a lowered immune system or are pregnant should not touch injection sites, used dressings and cleaning materials, or change your dressings or clean your injection sites.

Things to be careful of

If you have cold sores or other signs of herpes infection, use good hygiene habits and contact your doctor immediately.

Some of the symptoms of cold sores or herpes infection may include:

- pain, burning or tingling, in a blister around the mouth or genitals, or on the fingers or ears
- eye pain, light sensitivity, discharge from the eyes, redness of eye, watery or blurry vision
- flu-like illness (fever, chills, tiredness or headache)
- weakness in arms or legs

- other rare symptoms include mental confusion, memory loss and seizures.

Tell your doctor or nurse as soon as possible if your injection site is not healing.

Avoid direct contact of infants less than 3 months old to body fluids (eg blood, urine, saliva) of the treated patient, injection site or contaminated materials. If your infant shows signs of herpes infection, contact your doctor immediately.

Side effects

Tell your doctor, nurse or pharmacist as soon as possible if you do not feel well after being given Imlytic.

This medicine helps most people with melanoma, but it may have unwanted side effects in a few people.

All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical attention if you get some of the side effects.

Ask your doctor or pharmacist to answer any questions you may have.

Tell your doctor or pharmacist if you notice any of the following and they worry you:

- pain in general, after procedure, or in underarm, abdomen, limbs, groin, back, throat, tumour, ear
- tiredness or generally feeling unwell
- flu like illness, fever or chills, cough
- feeling sick or vomiting, stomach discomfort or diarrhoea
- constipation
- muscle pain or painful/swollen joints, bruising
- redness in the face
- dizziness
- headache
- areas of skin without any colour

- rash, inflamed skin, or worsening skin scaling
- feeling confused, anxious or feeling depressed
- difficulty falling asleep
- swelling of hands, ankles or feet without pain

The above list includes the more common side effects of your medicine. They are usually mild and short-lived.

Tell your doctor as soon as possible if you notice any of the following:

- dehydration
- weight loss
- fast heart rate

Tell your doctor immediately if any of the following happen:

- cold sores or other signs of herpes infection
- redness, swelling, discharge, or warmth at the injection site.

Tell your doctor immediately, or go to Accident and Emergency at your nearest hospital, if you notice any of the following:

- pain with swelling and tenderness in one of the legs
- shortness of breath or difficulty breathing

The above list includes serious side effects that may require medical attention or hospitalisation.

Tell your doctor if you notice anything that is making you feel unwell.

Other side effects not listed above may occur in some people. Tell your doctor if you notice anything that is making you feel unwell.

Do not be alarmed by this list of possible side effects.

You may not experience any of them.

Product description

What it looks like

Imlytic when thawed is a clear to semi-translucent or opaque liquid.

It is supplied in a single use vial, containing either:

- 1 million plaque forming units (PFU) in a volume of 1.0 mL or
- 100 million PFU in a volume of 1.0 mL.

Ingredients

Active ingredient: talimogene laherparepvec.

The other ingredients are:

- sodium phosphate - dibasic dihydrate
- sodium phosphate - monobasic dihydrate
- sodium chloride
- inositol
- sorbitol
- water for injections.

This medicine does not contain lactose, sucrose, gluten, tartrazine or any other azo dyes.

Manufacturer/Supplier

This medicine is made in the USA and supplied in Australia by:

Amgen Australia Pty Ltd
ABN 31 051 057 428
Level 7 123 Epping Road
North Ryde, NSW, 2113
This leaflet was prepared in December 2015.
Imlytic 1 million PFU
AUST R 232296
Imlytic 100 million PFU
AUST R 232297

Storing Imlytic

Imlytic is stored at the doctor's surgery or clinic, or at the pharmacy.

Disposal

Your doctor, nurse or pharmacist will dispose of this medicine.