

YOUR IMLYGIC® (talimogene laherparepvec; T-VEC) ACTION PLAN

(to be filled out by a member of your oncology team)

Patient Name _____ **Date** _____
Full Name *Today's Date*

Side effects discussed _____

Key points _____

AMGEN RESOURCES: **Financial Assistance**
Amgenassistonline.com or call 1-888-4ASSIST

TAKING THE MEDICATION

IMLYGIC® (talimogene laherparepvec; T-VEC) for Melanoma

HOW IT IS GIVEN:

- Imlygic is given by injection directly into a melanoma tumor. The first session is the longest—it will last about 2 hours, so plan accordingly.
- A second treatment will be given 3 weeks after the first treatment, and then every 2 weeks after that for as long as you have tumors.
- Your oncology team member will decide which tumors to inject and may not inject every tumor at every session.

THINGS TO TELL YOUR ONCOLOGIST'S OFFICE:

- If you are pregnant or breastfeeding.
- If you have a weakened immune system due to an immune deficiency, blood or bone marrow cancer, steroid use, organ or bone marrow transplant, or HIV/AIDS.
- If you are taking antiviral medications to treat or prevent herpes, such as acyclovir.
- If you are in close contact with someone who has a weakened immune system or is pregnant.

HOW TO TAKE IMLYGIC SAFELY (AND NOT SPREAD THE VIRUS):

The Imlygic medication is a modified version of the herpes simplex virus type 1, the virus that causes cold sores.

To prevent the Imlygic virus from spreading to other parts of your body or to your close contacts (such as people living in your house, caregivers, sex partners, or persons sharing the same bed), you should:

- Avoid any contact between your treatment sites, dressing(s), or body fluids and your close contacts (eg, you should use condoms when engaging in sexual activity and avoid kissing a close contact if you or they have an open mouth sore).
- Wear gloves while putting on or changing your dressing.
- 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.

TAKING THE MEDICATION

IMLYGIC® (talimogene laherparepvec; T-VEC) for Melanoma (Continued)

The table below gives you some commonly asked questions and answers about taking IMLYGIC safely:

| Question | Answer |
|---|---|
| I SHARE A SHOWER/TOOTHBRUSH/DISHES/LAUNDRY FACILITIES WITH OTHER PEOPLE. DOES THAT POSE A TRANSMISSION RISK? | Not unless you have uncovered, draining lesions or leave used dressing materials where others could come in contact with them. All lesions must be covered with an airtight and watertight dressing for 1 week after injection. Draining lesions must remain covered with an airtight and watertight dressing until they are no longer draining. Dressings should be changed once a week. |
| MY SPOUSE WILL BE CHANGING MY DRESSINGS. WHAT PRECAUTIONS MUST HE/SHE TAKE TO PREVENT TRANSMISSION? | <p>Caregivers should wear protective gloves when assisting patients in applying or changing dressings. Pregnant women and people with weakened immune systems should not serve as caregivers or have contact with wounds or dressings.</p> <p>Caregivers should be instructed to place used dressing materials, gloves, and anything in contact with the wound into a sealed plastic bag. That bag can be disposed of in household waste.</p> |
| MY PREGNANT DAUGHTER MAY BE CHANGING MY DRESSINGS. IS THAT A PROBLEM? | Pregnant women and people with weakened immune systems should not change dressings and must avoid contact with the injection site, anything that touches the injection site, and body fluids of patients treated with Imlygic. |
| IS IT A PROBLEM IF MY LESIONS ARE OOZING? | Not as long as they remain covered and no one who is pregnant or has a weakened immune system encounters the lesions. Draining lesions must remain covered with an airtight and watertight dressing until they are no longer draining. Dressing should be changed once a week. |
| WHAT IF MY LESIONS LEAK ONTO A COUNTER SURFACE, OR A BANDAGE WITH DRAINAGE TOUCHES THE BATHROOM VANITY? HOW DO I CLEAN IT UP? | Put on gloves and wipe down the surface with a 1:10 bleach solution (https://www.verywell.com/make-your-own-disinfectant-solution-998274). Use disposable materials for wiping, place in a sealed plastic bag, and throw them in the household trash. |
| WHAT PRECAUTIONS SHOULD MY FAMILY MEMBERS OR OTHER CLOSE CONTACTS AND I TAKE TO AVOID GETTING HERPES? | Household members, caregivers, sex partners, or persons sharing the same bed, pregnant women, and newborns should avoid contact with injected lesions, dressings, injection-site leakage, and body fluids of anyone treated with Imlygic. |
| HOW SHOULD I DISPOSE OF USED DRESSINGS, GLOVES, AND CLEANING MATERIALS? | Place used dressings and cleaning materials into a sealed plastic bag and dispose of in household waste. |

TAKING THE MEDICATION

IMLYGIC® (talimogene laherparepvec; T-VEC) for Melanoma (Continued)

If you or your partner becomes pregnant: Tell your oncologist's office right away if you or your partner becomes pregnant or you think you are pregnant while on this medication, as it may harm a developing baby. Also, remember to use condoms if you are sexually active, not only for birth control but to prevent exposure to body fluids.

Common side effects of this treatment: Even small side effects could be serious and you should report them all to your doctor or nurse. The most common side effects of Imlygic are:

- Flu-like symptoms
 - Chills
 - Fever
 - Aches
 - Tiredness
- Nausea
- Pain at the site of the injection
- Vomiting
- Diarrhea
- Headache
- Muscle and joint aches
- Pain in legs or arms

IMPORTANT SIDE EFFECTS

Your oncology team may discuss some side effects of Imlygic that can lead to serious problems if they aren't taken care of right away. These sections give information about possible symptoms, what you should tell your oncology team, when you should get medical help immediately, and any steps you can take to help ease the symptoms.

NAUSEA/VOMITING

IMLYGIC® (talimogene laherparepvec; T-VEC)
for Melanoma

Report immediately to your oncologist's office

What are the symptoms?

- Upset stomach
- Feeling like you are going to throw up
- Throwing up

What you should tell your oncology team member:

- When your symptoms started and how long they have lasted.
- If you have a fever, chills, and/or aches and pains as if you have the flu.
- How much and what you have been eating and drinking over the past 24 hours.
- If you might have been exposed to food poisoning or a stomach flu.

Red flags – Call your oncologist's office immediately – if they are not available, go directly to the Emergency Room.

- You've been throwing up for over a day or there is blood in your vomit.
- You have a fever over 104.0°F.
- You faint.

Managing Your Side Effects

- Take over-the-counter anti-nausea products or any medications prescribed by your oncology team and/or suck on a peppermint candy or chew peppermint gum.
- Before your second treatment, take any medications your oncology team has prescribed to prevent vomiting.
- Avoid solid foods. Instead eat soft, bland foods such as toast, pudding, rice, oatmeal, or crackers.
- Drink water, weak tea, clear broth, watered-down juice, or sports drinks (Gatorade®, Powerade®, and Pedialyte®), or suck on popsicles to prevent dehydration.

FLU-LIKE SYMPTOMS, FEVER WITH OR WITHOUT CHILLS

IMLYGIC[®] (talimogene laherparepvec; T-VEC)

for Melanoma

Report immediately to your oncologist's office

What are the symptoms?

- Temperature of 101.0°F or higher for more than 1 day
- Stomach upset/throwing up
- Chills
- Aches and pains
- Tiredness

What you should tell your oncology team member:

- What your temperature reading is.
- When the fever started and how long it has lasted.
- If you have any other symptoms, such as chills, stomach upset, vomiting, aches and pains, and feeling tired or just unwell.
- How much and what you have been drinking over the past 24 hours.
- If you have recently been around people with colds/flu or animals, or if you have traveled nationally or internationally.

Red flags – Call your oncologist's office immediately – if they are not available, go directly to the Emergency Room.

- You've been throwing up for over a day or there is blood in your vomit.
- If you have a fever over 104.0°F.
- You faint.
- You are dizzy and confused.
- Your heart feels like it is racing and you are breathing fast.

Managing Your Side Effects

- With the approval of your oncologist's office, take over-the-counter pain relievers such as acetaminophen (Tylenol[®]) or ibuprofen (Advil[®], Motrin[®]) every 6 hours until the fever goes away. Don't take more than 3,000 mg a day of acetaminophen or 2,400 mg a day of ibuprofen.
- Before your second treatment, take any medications your oncology team has prescribed such as acetaminophen or ibuprofen to prevent the flu-like symptoms.
- The night of treatment, consider using a heating blanket or multiple blankets to reduce the effect of any chills.
- Plan rest periods and some light exercise daily (like walking or yoga) to combat tiredness.
- Take a cool or slightly warm bath or put cool compresses or a cold pack on your forehead and neck to bring your fever down.
- Use warm packs and heated blankets if you have chills.
- Drink water and other liquids such as juice and sports drinks (Gatorade[®], Powerade[®], and Pedialyte[®]) or suck on popsicles to prevent dehydration.

HERPES INFECTION

IMLYGIC[®] (talimogene laherparepvec; T-VEC)
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Report immediately to your oncologist's office

What are the symptoms?

- Canker sores in the mouth, cold sores on the lips, blisters, or any tingling skin lesions in the mouth, on the lips, on the genitals, or on the fingers or ears
- A red, swollen area that is expanding, with or without a fever

What you should tell your oncology team member:

- When you first noticed the skin changes or sores, what they look like, and if they are painful.
- If you have flu-like symptoms (eg, fever, chills, stomach upset/throwing up, aches and pains, feeling unwell).
- If you have had any skin problems or herpes infection in the past.
- If you have noticed any changes in your vision/eyes (no matter how small), such as eye pain, sensitivity to light, discharge from the eyes, or blurry vision.
- If you have weakness in your arms or legs.
- If you feel very sleepy.
- If you feel foggy or confused.



Red flags – Call your oncologist's office immediately – if they are not available, go directly to the Emergency Room.

- If you have any eye symptoms.
- You have sores over a large area.
- You have fever, headache, confusion, and are sensitive to light or sound.

Managing Your Side Effects

- Follow your oncology team member's instructions for changing the bandage over your injection site. In general, you should keep it covered for 1 week.
- Wear gloves when changing your bandage.
- Do not touch or scratch the injection site or the bandage or allow anyone else to touch it without gloves.

INJECTION-SITE PAIN, SWELLING, OR INFECTION

IMLYGIC® (talimogene laherparepvec; T-VEC)
for Melanoma

Report immediately to your oncologist's office

What are the symptoms?

- Swelling or pain at the site where you received Imlygic injections
- Redness at the injection site, particularly if the redness appears to be expanding
- Warmth at the injection site
- Blisters
- Skin dimples (indentations)
- Red spots

What you should tell your oncology team member:

- When your symptoms started, how bad they are, and how long they have lasted.
- If you also have a fever, what the temperature is, and how long it's lasted.

Red flags – Call your oncologist's office immediately – if they are not available, go directly to the Emergency Room.

- Swelling, warmth, and redness around the injection site that is expanding quickly and a fever. This could be a sign of an infection called cellulitis.

Managing Your Side Effects

- As directed by your oncologist's office, take an anti-inflammatory pain reliever such as acetaminophen (Tylenol®) to reduce pain and swelling.
- Apply an ice pack to the area for 15 minutes several times a day.
- Keep the swollen area above your heart whenever you can to reduce swelling.
- Do not use elastic wrap or tape or otherwise compress the area as that may cause pain.



RESOURCES

Financial Assistance

Amgenassistonline.com or call 1-888- 4ASSIST

Additional Information Resources

AIM at Melanoma Foundation (Nurse on Call, patient symposia, drug resources, etc)
<http://www.AIMatMelanoma.org>