

**IMLYGIC**<sup>®</sup>:  
Designed to go straight  
at advanced melanoma!

Recurrent melanoma lesions after prior surgery  
Representative image

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## Your guide to understanding IMLYGIC<sup>®</sup> and what you might expect from treatment.

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### INDICATION

IMLYGIC<sup>®</sup> (talimogene laherparepvec) is a prescription medication injected on the skin, beneath the skin, or in your lymph nodes, to treat a type of skin cancer called melanoma when it can no longer be surgically removed.

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

Please see additional Important Safety Information on pages 18-19.

Compared to other types of skin cancer, melanoma is more likely to spread to other parts of the body. When this happens, melanoma becomes **metastatic melanoma**.<sup>2</sup>



If your melanoma has spread and cannot be removed by surgery, IMLYGIC<sup>®</sup> may be right for you. **IMLYGIC<sup>®</sup> is the first and only FDA-approved viral therapy that is injected directly into melanoma tumors.**<sup>1,3</sup> There, it multiplies inside the tumor cells and may trigger your immune system to fight the cancer.<sup>1,\*</sup>

So whether you are starting treatment with IMLYGIC<sup>®</sup> or talking about treatment options with your doctor, this brochure gives you information to help you make decisions that are right for you.

FDA=Food and Drug Administration.  
\*Exactly how IMLYGIC<sup>®</sup> works is not known.<sup>1</sup>

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### IMPORTANT SAFETY INFORMATION

You should not get IMLYGIC<sup>®</sup> 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).

## How IMLYGIC® is different

IMLYGIC® (pronounced "Im•LIE•jik") is used to treat **unresectable** melanoma in the skin or lymph glands. It's the **first and only** FDA-approved cancer treatment of its kind.<sup>1,3</sup>

- ✦ IMLYGIC® is made by modifying—or changing—the herpes simplex virus type 1, the common virus known to cause cold sores<sup>1</sup>
- ✦ IMLYGIC® treatment is targeted and precise\*—it's injected directly into tumors by your healthcare provider<sup>1</sup>
- ✦ IMLYGIC® attacks cancer cells differently because it is injected into tumor cells, which destroys them. This triggers an immune response.<sup>1,\*</sup> For an illustration of how IMLYGIC® is thought to work, see the next page
- ✦ Most side effects with IMLYGIC® are mild to moderate and generally go away within 3 days<sup>1</sup>
- ✦ Common side effects include tiredness, chills, fever, nausea, flu-like symptoms, and pain at treatment site<sup>1</sup>

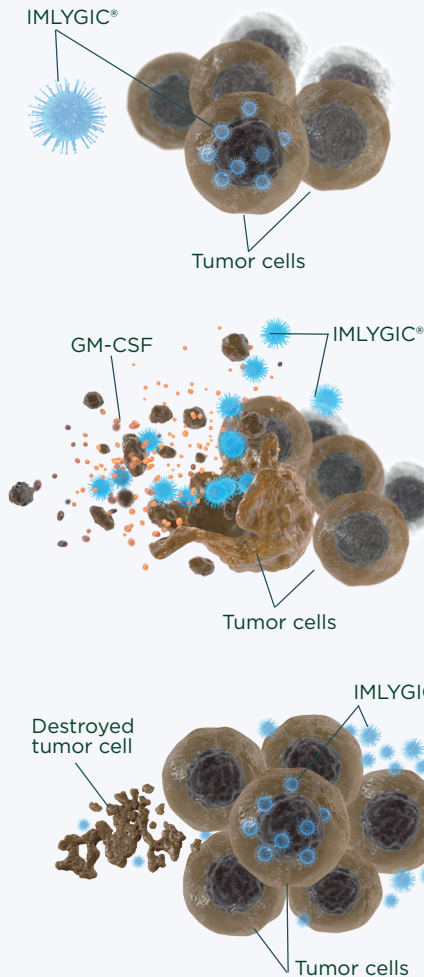
\*Exactly how IMLYGIC® works is not known.<sup>1</sup>

### IMPORTANT SAFETY INFORMATION

- IMLYGIC® is a weakened form of Herpes Simplex Virus Type 1, which is commonly called the cold sore virus. Your health care provider will inject IMLYGIC® directly into your tumor(s).
- Your health care 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 health care provider will show you how to do this.

## A closer look at how IMLYGIC® works

IMLYGIC® is injected directly into the tumor. It's thought to work by destroying tumor cells and triggering an immune response.<sup>1,4</sup>



IMLYGIC® is injected directly into melanoma tumors on your skin or lymph glands.<sup>1</sup>

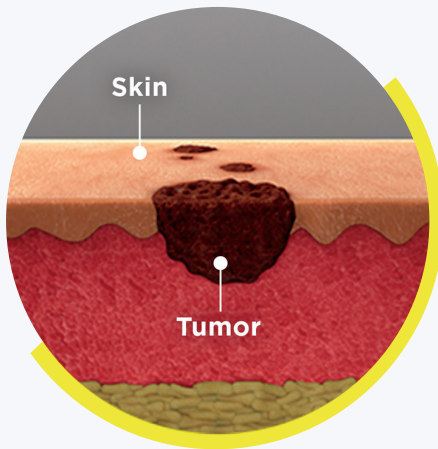
IMLYGIC® multiplies inside the tumor cells and may trigger your immune system to fight the cancer.<sup>1</sup>

IMLYGIC® continues to invade neighboring tumor cells.<sup>1,4</sup>

The images above are only intended to help describe how IMLYGIC® is thought to work. Exactly how IMLYGIC® works is unknown.

GM-CSF=Granulocyte-Macrophage Colony-Stimulating Factor.

## IMLYGIC® can be injected into 3 kinds of melanoma tumors

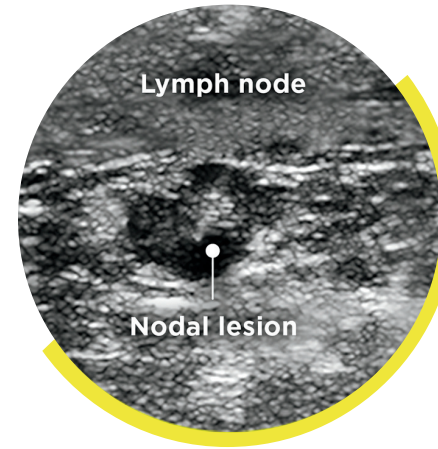
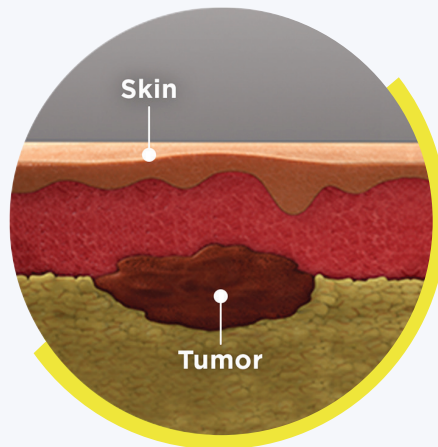


### Tumors on the surface of the skin.

These are called **cutaneous** (pronounced kyoo-TANE-ee-us) lesions.<sup>1</sup>

### Tumors just under the surface of the skin.

These are called **subcutaneous** (SUB-kyoo-TANE-ee-us) lesions.<sup>1</sup>



### Tumors that have spread to lymph nodes.

These are called **nodal lesions**. The doctor sees or feels these tumors, or uses an ultrasound to find them.<sup>1</sup>

IMLYGIC® is the first and only FDA-approved viral therapy that is injected directly into melanoma tumors.<sup>1,3</sup> Talk with your doctor to see if IMLYGIC® is right for you.

### IMPORTANT SAFETY INFORMATION

The 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. You should share this information with them:

- 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 of you has an open mouth sore).

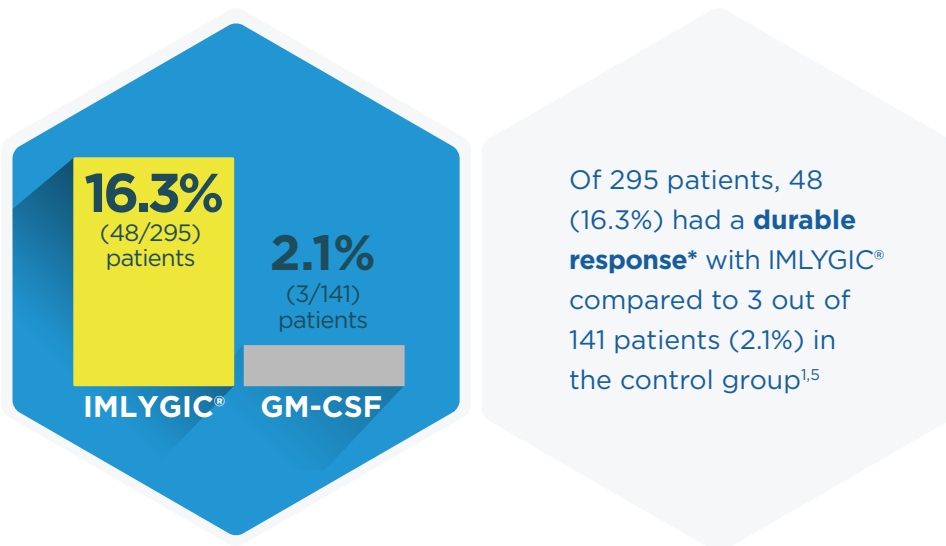
### IMPORTANT SAFETY INFORMATION

- Don't touch or scratch the parts of your body that have been injected with IMLYGIC®.
- 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).
- Replace dressings right away with a clean dressing if they become loose or come off.
- Place all used dressings and cleaning materials in a sealed plastic bag, and throw them away in the garbage.

Please see additional Important Safety Information on pages 18-19.

## IMLYGIC® has results that last for 6 months or longer<sup>1</sup>

Patients who take IMLYGIC® may experience shrinkage or disappearance of their tumors for 6 continuous months or longer.<sup>1,5,6</sup>



\*Unadjusted Relative Risk 7.6 (95%, CI: 2.4, 24.1),  $P < 0.0001$ .

### IMPORTANT SAFETY INFORMATION

- Common side effects of IMLYGIC® include tiredness, chills, fever, nausea, flu-like symptoms, and 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), or mental confusion.

IMLYGIC® was studied in 436 patients with Stage IIIB/C and Stage IV melanoma against a control group given another treatment called Granulocyte-Macrophage Colony-Stimulating Factor, or GM-CSF.<sup>1,†</sup>

- \* Of the 48 patients who achieved a durable response with IMLYGIC®, 14 patients (29.1%) had a **durable complete response**. This means that all evidence of tumors disappeared for 6 months or longer<sup>6,7</sup>
- \* Of the 48 patients who achieved a durable response with IMLYGIC®, 34 patients (70.8%) had a **durable partial response**. This means the size of all tumors that could be measured was reduced by 50% or more for 6 months or longer<sup>6,7</sup>
- \* Of the 3 patients in the control group who achieved a durable response as previously described, all of them had a durable partial response. This means the size of all tumors that could be measured was reduced by 50% or more for 6 months or longer<sup>6,7</sup>

†IMLYGIC® was injected into tumors for at least 6 months or until there were no injectable lesions, and the control group was given GM-CSF subcutaneously (under the skin).

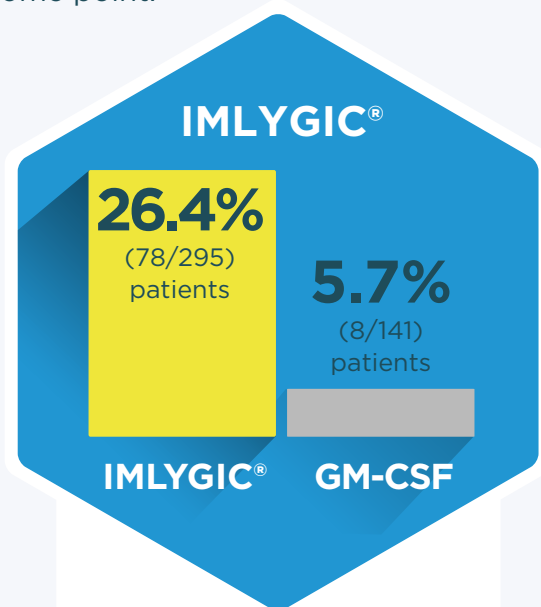
### IMPORTANT SAFETY INFORMATION

- If you think you have a herpes infection, inform your health care 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 health care 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.
- Tell your health care provider if you have any side effect that bothers you or does not go away.
- These are not all the possible side effects of IMLYGIC®.

If you would like more information, talk with your health care provider.

## Tumors may shrink by at least half their size<sup>5,6</sup>

Some patients who take IMLYGIC<sup>®</sup> may also see an **overall response**.\* This means that tumors may shrink by at least half their size at some point.<sup>5,6</sup>



**1 in 4 patients**  
(78 out of 295, or 26.4%)  
**saw their tumors shrink**  
**by at least half,**  
compared with 1 in 20  
(8 out of 141, or 5.7%)  
in the control group<sup>5</sup>

\*Overall response rate was a secondary endpoint of the study. This means that while the study was not designed to assess overall response, it was still a measurable result in the study. Overall response rate is the percentage of patients that had either a complete response or a partial response.<sup>5</sup>

## On average, patients taking IMLYGIC<sup>®</sup> could see a response by 4.1 months<sup>1</sup>



**Some people began to respond to treatment as early as 1.2 months, and others as late as 16.7 months.**<sup>1</sup> It is important for your doctor to monitor your condition regularly to see how your body is responding.

This time to response was another secondary endpoint of the study.<sup>5</sup>

Existing tumors may increase in size and new tumors could appear during treatment with IMLYGIC<sup>®</sup> prior to seeing a response.<sup>1</sup>

### IMPORTANT SAFETY INFORMATION

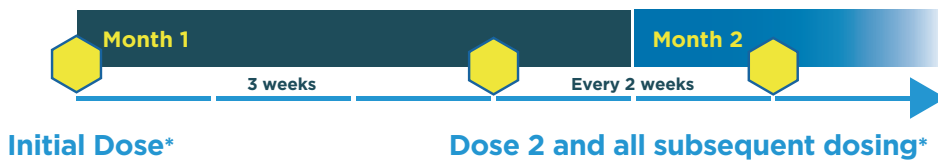
Because IMLYGIC<sup>®</sup> may affect the way other medicines work and other medicines may affect how IMLYGIC<sup>®</sup> works, tell your doctor about all the medications you take.

## Getting started with IMLYGIC®<sup>1</sup>

Once your doctor has prescribed IMLYGIC®, there are a few things you may want to consider:

**The first 2 treatments of IMLYGIC® are given 3 weeks apart.**

After that, IMLYGIC® will be administered every 2 weeks\* for as long as there are injectable tumors. You can get treated for 6 months or longer.



\*According to your physician's instruction.

### On the day of injection, know what to expect.



IMLYGIC® is injected by a healthcare professional in a doctor's office



The healthcare professional will inject IMLYGIC® directly into one or more tumors using a needle and syringe. If lesions are clustered together, they will be injected as if they are one lesion



The amount of IMLYGIC® injected is based on the number and size of the tumors and will be determined by your doctor before the injection of IMLYGIC®



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

## Managing your care during and after treatment<sup>1</sup>

### Important things to know while being treated with IMLYGIC®:

IMLYGIC® virus can spread to other areas of your body or to people close to you (household members, caregivers, sex partners, or people you share a bed with).

To avoid spreading IMLYGIC® to other areas of your body or to others:



Avoid direct contact between your treatment sites, dressings, or body fluids and people close to you (for example, use condoms when engaging in sexual activity, and avoid kissing close contacts if either of you has an open mouth sore)



Don't touch or scratch the parts of your body that have been injected with IMLYGIC®



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)



Replace dressings right away with a clean dressing if they become loose or come off



Place all used dressings and cleaning materials in a sealed plastic bag, and throw them away in the garbage

This section is for informational purposes only. Please talk with your doctor to find out if IMLYGIC® is the right treatment option for you.

## Other considerations with IMLYGIC®<sup>1</sup>

### Before getting IMLYGIC® treatment, tell your healthcare provider:



About any other medicines you're taking



If you're taking steroids or medicines that suppress your immune system, or antiviral medications, like acyclovir, to treat or prevent herpes

If you 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



If you have contact with people close to you who have a weakened immune system or are pregnant



IMLYGIC® may harm your unborn baby. Tell your doctor if you are pregnant or plan to become pregnant, nursing, or planning to breastfeed. You should not become pregnant during treatment with IMLYGIC®. Your doctor will determine whether you should receive IMLYGIC®

## Other considerations with IMLYGIC® (continued)<sup>1</sup>



Talk to your healthcare provider about effective birth control methods



**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





## Patient resources

### The Amgen® SupportPlus Co-Pay Program\*

**AMGEN** Support<sup>+</sup> The Amgen SupportPlus Co-Pay Program may help eligible commercially insured patients lower their out-of-pocket prescription costs.

\*Eligibility criteria and program maximums apply. See [AmgenSupportPlus.com/copay](https://AmgenSupportPlus.com/copay) for full Terms and Conditions.

### ADDITIONAL FINANCIAL SUPPORT



Amgen SupportPlus can provide information about independent nonprofit foundations that may be able to help.<sup>†</sup>

<sup>†</sup>Eligibility for resources provided by independent nonprofit patient assistance programs is based on the nonprofit's criteria. Amgen has no control over these programs and provides information as a courtesy only.

### AMGEN® NURSE PARTNERS<sup>‡</sup>



Dedicated Amgen Nurse Partners will be with you along the way to offer supplemental support and provide information about resources to help you access your prescribed Amgen medication.

Amgen Nurse Partners can provide supplemental support, including:

- Guidance on resources that may help lower out-of-pocket medication costs
- Assistance to help you stay on track with your medication
- Answers to your questions about Amgen SupportPlus

<sup>‡</sup>Amgen Nurse Partners are only available to patients that are prescribed certain Amgen products. They are not part of your treatment team and do not provide medical advice, nursing, or case management services. Amgen Nurse Partners will not inject patients with Amgen medications. Patients should always consult their healthcare provider regarding medical decisions or treatment concerns.

For more information, contact us at  
**866-264-2778**

### Finding a support network

Fighting melanoma can be a challenge. It is important to have a support network to rely on during this difficult time. There are many options—here are a few that may help.



The **AIM at Melanoma Foundation** is an organization that provides information, support, educational symposia, and more for melanoma patients and their caregivers.<sup>8</sup>



The **Melanoma International Foundation** offers guidance to melanoma patients and their loved ones with services that include patient outreach/support via email, a helpline, and an online forum.<sup>9</sup>



The **Melanoma Research Alliance (MRA)** funds research projects with the goal of making advances in the prevention, diagnosis, and treatment of melanoma. MRA partners with individuals, private foundations, and corporations on various initiatives, including public awareness campaigns.<sup>10</sup>



Visitors to the **Melanoma Research Foundation** website will find resources and tools for melanoma patients, including a treatment center finder, a Phone Buddy Program, an Ask a Nurse email program, and an online patient community.<sup>11</sup>

These resources are provided for your information. Amgen does not endorse or control the content of the third-party patient support sites listed above.

## IMPORTANT SAFETY INFORMATION

### What is IMLYGIC® used for?

IMLYGIC® (talimogene laherparepvec) is a prescription medication used to treat a type of skin cancer called melanoma when it is on your skin or in your lymph glands.

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

### What is IMLYGIC® made from and how is it given?

- IMLYGIC® is a weakened form of Herpes Simplex Virus Type 1, which is commonly called the cold sore virus. Your health care provider will inject IMLYGIC® directly into your tumor(s).
- Your health care 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 health care provider will show you how to do this.

### Who should not take 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 you tell your health care provider before getting IMLYGIC®?

- Because IMLYGIC® may affect the way other medicines work and other medicines may affect how IMLYGIC® works, tell your doctor about all the medications you take.
- Because certain medications can affect your immune system, or affect how IMLYGIC® works, tell your doctor if you are taking steroids or are taking antiviral medications to treat or prevent herpes, like acyclovir.
- Tell your doctor if you have or ever had certain medical conditions like: HIV infection or AIDS, blood or bone marrow cancer, autoimmune disease, or other medical conditions that can weaken your immune system.
- Tell your doctor if you have close contact with someone who has a weakened immune system or is pregnant.
- IMLYGIC® may harm your unborn baby. Tell your doctor if you are pregnant or planning to become pregnant, nursing, or planning to breastfeed. Your doctor will determine whether you should receive IMLYGIC®.
- Talk with your health care provider about effective birth control methods.

**The 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. You should share this information with them:**

- 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 of you has an open mouth sore).
- Don't touch or scratch the parts of your body that have been injected with IMLYGIC®.
- 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).
- Replace dressings right away with a clean dressing if they become loose or come off.
- Place all used dressings and cleaning materials in a sealed plastic bag, and throw them away in the garbage.

### What are the possible side effects of IMLYGIC®?

- Common side effects of IMLYGIC® include tiredness, chills, fever, nausea, flu-like symptoms, and 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
  - Mental confusion
- If you think you have a herpes infection, inform your health care 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 health care 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.
- Tell your health care provider if you have any side effect that bothers you or does not go away.
- These are not all the possible side effects of IMLYGIC®.

If you would like more information, talk with your health care provider.

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit [www.fda.gov/medwatch](http://www.fda.gov/medwatch), or call 1-800-FDA-1088.

Please click [here](#) to see full Prescribing Information, including Medication Guide, for IMLYGIC®.

### INDICATION

IMLYGIC® (talimogene laherparepvec) is a prescription medication injected on the skin, beneath the skin, or in your lymph nodes, to treat a type of skin cancer called melanoma when it can no longer be surgically removed.

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

Visit **IMLYGIC.com** to learn more

**References:** 1. IMLYGIC® (talimogene laherparepvec) Prescribing Information, BioVex, Inc., a subsidiary of Amgen, Inc. 2. PubMed Health. U.S. National Library of Medicine. Melanoma treatment. <https://www.ncbi.nlm.nih.gov/pubmedhealth/PMH0032763/>. Accessed on January 9, 2019. 3. FDA approves first oncolytic virus therapy: IMLYGIC® for melanoma. Oncology Times. [https://journals.lww.com/oncology-times/Fulltext/2015/12100/FDA\\_Approves\\_First\\_Oncolytic\\_Virus\\_Therapy\\_27.aspx](https://journals.lww.com/oncology-times/Fulltext/2015/12100/FDA_Approves_First_Oncolytic_Virus_Therapy_27.aspx). Accessed on January 9, 2019. 4. Liu BL, Robinson M, Han ZQ, et al. ICP34.5 deleted herpes simplex virus with enhanced oncolytic, immune stimulating, and anti-tumour properties. *Gene Ther.* 2003;10:292-303. 5. Andtbacka RHI, Kaufman HL, Collichio F, et al. Talimogene laherparepvec improves durable response rate in patients with advanced melanoma. *J Clin Oncol.* 2015;33:2780-2788. 6. Andtbacka RHI, Kaufman HL, Collichio F, et al. Talimogene laherparepvec improves durable response rate in patients with advanced melanoma. *J Clin Oncol.* 2015;33(suppl Clinical Study Protocol):doi:10.1200/JCO.2014.58.3377. 7. Data on file, Amgen; 2017. 8. AIM at Melanoma. AIM mission. <http://www.aimatmelanoma.org/aim-mission>. Accessed on January 9, 2019. 9. Melanoma International Foundation. Programs & services. <http://melanomainternational.org/who-we-are/programs/#.Veo5519Lhdg>. Accessed on January 9, 2019. 10. Melanoma Research Alliance. <http://curemelanoma.org/about-mra/mra-overview/>. Accessed on January 9, 2019. 11. Melanoma Research Foundation. <http://www.melanoma.org/find-support>. Accessed on January 9, 2019.



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