## INDICATION

IMLYGIC® is a genetically modified oncolytic viral therapy indicated for the local treatment of unresectable cutaneous, subcutaneous, and nodal lesions in patients with melanoma recurrent after initial surgery.

Limitations of use: IMLYGIC® has not been shown to improve overall survival or have an effect on visceral metastases.

IMLYGIC®
(talimogene laherparepvec)
SUSPENSION FOR INJECTION
$10^6$ PFU/mL and $10^8$ PFU/mL single-use vials

# PRODUCT ORDERING INFORMATION

## PRODUCT INFORMATION

**NDC**
55513-078-01

**DESCRIPTION**
$10^6$ (1 million) PFU/mL
in single-use 1 mL vial

**QUANTITY***
One per carton

**NDC**
55513-079-01

**DESCRIPTION**
$10^8$ (100 million) PFU/mL
in single-use 1 mL vial

**QUANTITY***
One per carton

Discard after expiry date printed on the vial label.

## IMLYGIC® ORDERING INFORMATION

| AUTHORIZED DISTRIBUTORS | | |
|---|---|---|
| ASD Healthcare | 1-800-746-6273 | https://www.asdhealthcare.com |
| Cardinal Health Specialty Distribution | 1-866-677-4844 | http://orderexpress.cardinalhealth.com |
| M&D Specialty Distribution, LLC | 1-800-710-6100 | http://www.mdspecialtydist.com |
| McKesson Plasma and Biologics<br>*Online orders for existing customers:* | 1-877-625-2566 | http://mckesson.com/plasmabiologics<br>http://connect.mckesson.com |
| McKesson Specialty Health | 1-800-482-6700 | http://mscs.mckesson.com |
| Oncology Supply | 1-800-633-7555 | custserv@oncologysupply.com |
| Smith Medical Partners | 1-800-292-9653 | https://www.smpspecialty.com |

### IMLYGIC® DELIVERY SCHEDULE

| Order IMLYGIC® on This Day (in the AM EST) | MON | TUE | WED | THU | FRI |
|---|---|---|---|---|---|
| Receive IMLYGIC® by 10:30 AM Local Time on This Day | WED | THU | FRI | TUE | TUE |

- If your facility does not have access to a -80°C freezer, please schedule treatments from Tuesday afternoon through Friday, as deliveries do not take place on Monday.
- AMGEN does not process orders on the following holidays: New Year's Day, Martin Luther King Day, Memorial Day, Independence Day, Labor Day, Thanksgiving Day, the day after Thanksgiving, Christmas Eve, Christmas Day.
- IMLYGIC® may only be ordered through an authorized distributor, who will then coordinate the shipment with AMGEN.

**Please click here for full Prescribing Information**

**Please click here for Important Safety Information**

*Minimum Ordering Quantity.

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SUSPENSION FOR INJECTION
$10^6$ PFU/mL and $10^8$ PFU/mL single-use vials

# IMLYGIC® PRODUCT STORAGE INFORMATION

IMLYGIC® must be stored and transported frozen at **-90°C to -70°C (-130°F to -94°F)**.

- Store in the original carton in order to protect from light
- Thaw IMLYGIC® immediately prior to administration
- IMLYGIC® should only be exposed to room temperature (20°C to 25°C [68°F to 77°F]) during thawing and administration
- Please follow Special Instructions for Use and Handling as outlined in the full Prescribing Information

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- Detailed instructions on transferring IMLYGIC® to an ultra-low freezer are shipped with the product
- If your institution does not have an ultra-low freezer to store IMLYGIC®, there are **2 options available to you:**

## IMLYGIC® STORAGE CONTAINER

- IMLYGIC® is shipped in a **-90°C to -70°C storage container** that may be used to store the product for **up to 96 hours** after it is sealed for delivery. The date and time for when the container is sealed is printed on the outside of the shipment
- Detailed instructions on storing and handling IMLYGIC® are shipped with the product

## IMLYGIC® FREEZER PROGRAM


If your institution does not have an ultra-low freezer available for storage of IMLYGIC®, a Stirling Shuttle -86°C Portable Ultra Low Temperature Freezer can be provided when you purchase IMLYGIC®. For more information, call 1-866-IMLYGIC (465-9442); choose Option 1 for Healthcare Providers, then Option 2 for ordering.

**Stirling Shuttle -86°C Portable Ultra Low Temperature Freezer**

| | |
|---|---|
| Operating Voltage | 100-240 V, AC, 50/60 Hz |
| Exterior Dimensions | 27.3" L x 13.8" W x 18.1" H |
| Net Weight, Empty | 46 lbs (21 kg) |

**Please click here for full Prescribing Information**

**Please click here for Important Safety Information**

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## IMPORTANT SAFETY INFORMATION

**Contraindications**

- Do not administer IMLYGIC® to immunocompromised patients, including those with a history of primary or acquired immunodeficient states, leukemia, lymphoma, AIDS or other clinical manifestations of infection with human immunodeficiency viruses, and those on immunosuppressive therapy, due to the risk of life-threatening disseminated herpetic infection.
- Do not administer IMLYGIC® to pregnant patients.

**Warnings and Precautions**

- **Accidental exposure to IMLYGIC®** may lead to transmission of IMLYGIC® and herpetic infection, including during preparation and administration. Health care providers, close contacts, pregnant women, and newborns should avoid direct contact with injected lesions, dressings, or body fluids of treated patients. The affected area in exposed individuals should be cleaned thoroughly with soap and water and/or a disinfectant.
- Caregivers should wear protective gloves when assisting patients in applying or changing occlusive dressings and observe safety precautions for disposal of used dressings, gloves, and cleaning materials. Exposed individuals should clean the affected area thoroughly with soap and water and/or a disinfectant.
- To prevent possible inadvertent transfer of IMLYGIC® to other areas of the body, patients should be advised to avoid touching or scratching injection sites or occlusive dressings.
- **Herpetic infections:** Herpetic infections (including cold sores and herpetic keratitis) have been reported in IMLYGIC®-treated patients. Disseminated herpetic infection may also occur in immunocompromised patients. Patients who develop suspicious herpes-like lesions should follow standard hygienic practices to prevent viral transmission.
- Patients or close contacts with suspected signs or symptoms of a herpetic infection should contact their health care provider to evaluate the lesions. Suspected herpetic lesions should be reported to Amgen at 1-855-IMLYGIC (1-855-465-9442). Patients or close contacts have the option of follow-up testing for further characterization of the infection.
- IMLYGIC® is sensitive to acyclovir. Acyclovir or other antiviral agents may interfere with the effectiveness of IMLYGIC®. Consider the risks and benefits of IMLYGIC® treatment before administering antiviral agents to manage herpetic infection.
- **Injection Site Complications:** Necrosis or ulceration of tumor tissue may occur during IMLYGIC® treatment. Cellulitis and systemic bacterial infection have been reported in clinical studies. Careful wound care and infection precautions are recommended, particularly if tissue necrosis results in open wounds.
- Impaired healing at the injection site has been reported. IMLYGIC® may increase the risk of impaired healing in patients with underlying risk factors (eg, previous radiation at the injection site or lesions in poorly vascularized areas). If there is persistent infection or delayed healing of the injection site, consider the risks and benefits of continuing treatment.
- **Immune-Mediated events** including glomerulonephritis, vasculitis, pneumonitis, worsening psoriasis, and vitiligo have been reported in patients treated with IMLYGIC®. Consider the risks and benefits of IMLYGIC® before initiating treatment in patients who have underlying autoimmune disease or before continuing treatment in patients who develop immune-mediated events.
- **Plasmacytoma at the Injection Site:** Plasmacytoma in proximity to the injection site has been reported in a patient with smoldering multiple myeloma after IMLYGIC® administration in a clinical study. Consider the risks and benefits of IMLYGIC® in patients with multiple myeloma or in whom plasmacytoma develops during treatment.
- **Obstructive Airway Disorder:** Obstructive airway disorder has been reported following IMLYGIC® treatment. Use caution when injecting lesions close to major airways.
- **Hepatic Hemorrhage from Transcutaneous Intrahepatic Route of Administration:** IMLYGIC® is not indicated for transcutaneous intrahepatic route of administration. In clinical studies, cases of hepatic hemorrhage resulting in hospitalization and death have been reported in patients receiving transcutaneous intrahepatic IMLYGIC® injections.

**Adverse Reactions**

- The most commonly reported adverse drug reactions (≥ 25%) in IMLYGIC®-treated patients were fatigue, chills, pyrexia, nausea, influenza-like illness, and injection site pain. Pyrexia, chills, and influenza-like illness can occur at any time during IMLYGIC® treatment, but were more frequent during the first 3 months of treatment.
- The most common Grade 3 or higher adverse reaction was cellulitis.

**Supplied and Marketed by:**
Amgen, Inc.
www.amgen.com

**For more information about IMLYGIC®, Ordering or Returns, please:**
Call **1-866-IMLYGIC (465-9442)**
Visit: www.IMLYGIC.com

**For Billing and Reimbursement Assistance, please:**
Contact Amgen Assist® at **1-888-4ASSIST**
Visit: www.AmgenAssistOnline.com

**Reference:** IMLYGIC® (talimogene laherparepvec) Prescribing Information. Amgen.

**Please click here for full Prescribing Information**

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