

Patient Education Brochure

INFORMATION FOR PATIENTS AND CLOSE CONTACTS

This brochure contains important safety information you should know before and during IMLYGIC® treatment.

Please read this information carefully before and after each treatment.

Please also read the IMLYGIC® Package Leaflet that will be handed to you by your healthcare professional and is also available online at <https://www.medicines.org.uk/emc/>.

Talk to your doctor or nurse if you have any questions or concerns about your treatment.

WHAT SHOULD I KNOW ABOUT IMLYGIC®?

- IMLYGIC® is a weakened form of herpes simplex virus type 1 (HSV-1), which is commonly called the cold sore virus, and is used to treat a type of skin cancer called melanoma.
- IMLYGIC® may cause life-threatening herpes infection. It is more common in patients with a **weakened immune system**.
- IMLYGIC® should **not be used during pregnancy** unless the potential benefit to the patient justifies the potential risk to the unborn baby.
- IMLYGIC® may **harm your unborn baby**. Tell your doctor if you are pregnant or plan to become pregnant.
- During or after IMLYGIC® treatment, you could develop cold sores or a **more serious herpes infection** that could spread to other parts of your body.
- IMLYGIC® virus could be **spread to your close contacts** (household members, caregivers, sex partners, or someone you share a bed with) if they have **direct contact** with your body fluids or injection sites.
- You should share this information with your close contacts, particularly if they are pregnant or have a weakened immune system.
- Injected sites should be covered with airtight and watertight dressings at all times. Apply the dressing as instructed by your healthcare professional and ask your healthcare professional how long the injection site should be covered for. If the dressing comes loose or falls off, replace it right away with a clean dressing.

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, redness of eye, tearing, or blurry vision
- Weakness in arms or legs
- Extreme drowsiness (feeling sleepy)
- Fever associated with headache
- Vomiting
- Mental confusion
- Memory loss
- Seizures

IF YOU HAVE ANY OF THESE SYMPTOMS OR ANY NEW SYMPTOMS DURING OR AFTER TREATMENT WITH IMLYGIC®, TELL YOUR DOCTOR RIGHT AWAY.

Any lesion that forms can be tested to determine if it is caused by IMLYGIC®

Please continue to reverse side for additional information.

WHAT SHOULD I DO DURING TREATMENT WITH IMLYGIC®?

- Avoid direct contact between injection sites or body fluids of patients and close contacts:
 - The treated patient should **minimise the risk of exposure** of blood and body fluids to close contacts for the duration of IMLYGIC® treatment, and through **30 days after the last dose of IMLYGIC®**. This is done by observing the following:
 - Do not engage in sexual intercourse without a latex condom
 - Do not kiss if either of you has an open mouth sore
 - Do not share cutlery, crockery, and drinking vessels
 - Do not share injection needles, razorblades, and toothbrushes
 - Do not touch or scratch the injection site.
- Keep injection sites covered with airtight and watertight dressings at all times. If the injection site is weeping or oozing keep the dressing on until the weeping or oozing stops. Apply dressing as instructed by your healthcare professional. 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 household waste, to keep household contacts from directly touching them.

WHAT SHOULD I TELL MY CLOSE CONTACTS WHILE I AM BEING TREATED WITH IMLYGIC®?

- Avoid direct contact with your body fluids or injection sites.
- Wear gloves while changing your dressing.
- Clean the affected area with soap and water and/or a disinfectant in case of accidental exposure to IMLYGIC®. If they develop signs or symptoms of herpes infection, you should ask them to call their doctor.
- Suspected herpetic lesions in close contacts can be tested to determine if it is caused by IMLYGIC®.

**If your close contact is pregnant or has a weakened immune system,
they should not change your dressings or clean your injection sites.**

TALK WITH YOUR DOCTOR OR NURSE IF YOU HAVE ANY QUESTIONS ABOUT TREATMENT WITH IMLYGIC®.

Reporting of side effects:

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at <https://yellowcard.mhra.gov.uk> or search for MHRA Yellow Card in the Google Play or Apple Store. By reporting side effects you can help provide more information on the safety of this medicine. Side effects should also be reported to Amgen Limited on +44 (0) 1223 436441.

Always provide the batch number from your Patient Alert Card when reporting side effects. Keep all your alert cards, even those that are old, to maintain a record of all the IMLYGIC® batches you have received.

This brochure does not include all the important safety information you need to know about IMLYGIC®. Please refer to the IMLYGIC® Package Leaflet that will be handed to you by your healthcare professional for more information and is also available online at <https://www.medicines.org.uk/emc/>. You should read this at the time of each injection because the information may change over time.