

INFORMATION FOR PATIENTS AND CLOSE CONTACTS

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This brochure contains important safety information you should know before and during IMLYGIC[®] treatment. Please read this information carefully before and after each treatment. If you have any further questions or concerns about the treatment please refer to your doctor or nurse.

WHAT SHOULD I KNOW ABOUT IMLYGIC[®]?

- IMLYGIC[®] is a weakened form of herpes simplex virus type 1 (HSV-1), which is also called the cold sore virus.
- IMLYGIC[®] may cause life-threatening herpes infection in persons with weakened immune systems.
- 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 herpes sores or a more serious herpes infection.
- IMLYGIC[®] virus could infect 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. If the dressing comes loose or falls off, replace it right away with a clean dressing.

WHAT ARE SIGNS AND SYMPTOMS OF HERPES INFECTION?

- Pain, burning or tingling in a blister around the mouth or genitals, or on the finger or ears with or without a scab
- 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 DURING OR AFTER TREATMENT WITH IMLYGIC[®],
TELL YOUR DOCTOR RIGHT AWAY.**

Please continue to reverse side for additional information.

WHAT SHOULD I DO TO AVOID SPREADING IMLYGIC®?

- Avoid direct contact between injection sites or body fluids with close contacts:
 - The treated patient should minimize the risk of exposure of blood and body fluids to close contacts for the duration of IMLYGIC® treatment through 30 days after the last administration of IMLYGIC®. The following activities should be avoided:
 - Sexual intercourse without a latex condom
 - Kissing if either of you has an open mouth sore
 - Common usage of cutlery, crockery, and drinking vessels
 - Common usage of injection needles, razorblades, and toothbrushes
- Avoid touching or scratching the injection sites.
- 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.

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®.

You can help by reporting any side effects you may get. Adverse events can be reported to the Ministry of Health via the on-line form for adverse events reporting, that is located on the Ministry of Health home page www.health.gov.il or by entering the link:
<https://forms.gov.il/globaldata/getsequence/getsequence.aspx?formType=AdversEffectMedic@moh.gov.il>
Or report to the local distributor Medison using the following email address: pv@Medison.co.il
Always provide the batch number from your Patient Safety Information Card when reporting side effects.