

## PATIENT MEDICATION INFORMATION

### READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

PrOMVOH™

mirikizumab injection

**Read this carefully before you start taking OMVOH and each time you get a refill. This leaflet is a summary and will not tell you everything about this drug. Talk to your healthcare professional about your medical condition and treatment and ask if there is any new information about Omvoh.**

#### What is Omvoh used for?

- Omvoh contains the active substance 'mirikizumab', a monoclonal antibody. Monoclonal antibodies are proteins that recognise and bind specifically to certain proteins in the body.
- Omvoh works by stopping a protein in the body called 'IL-23', which causes inflammation.
- Ulcerative colitis is an inflammatory disease of the large bowel. If you have ulcerative colitis, you will first be given other medicines. If you do not respond well enough or cannot tolerate these medicines, you may be given Omvoh to reduce signs and symptoms of ulcerative colitis such as diarrhea, rectal bleeding, and urgency.

#### How does Omvoh work?

Omvoh contains the active substance 'mirikizumab', a monoclonal antibody. Monoclonal antibodies are proteins that recognize and bind specifically to certain proteins in the body.

Omvoh works by stopping a protein in the body called 'IL-23', which causes inflammation.

#### What are the ingredients in Omvoh?

Medicinal ingredients: mirikizumab

Non-medicinal ingredients: citric acid anhydrous, polysorbate 80, sodium chloride, sodium citrate dihydrate, and water for injection.

#### Omvoh comes in the following dosage forms:

Intravenous Infusion:

- Single-use vial: 20 mg/mL (300 mg/15 mL)

Subcutaneous Injection

- Prefilled syringe: 100 mg/mL
- Prefilled pen: 100 mg/mL

#### Do not use Omvoh if:

- You are allergic to mirikizumab or any of the other ingredients of this medicine. See **What are the ingredients in Omvoh?**
- If you have important active infections.

**To help avoid side effects and ensure proper use, talk to your healthcare professional before you take Omvoh. Talk about any health conditions or problems you may have, including if you:**

- currently have an infection or if you have an infection that keeps coming back. Omvoh may lower your ability to fight infections and may increase your risk of infections.
- have tuberculosis (TB) or have been in close contact with someone with TB.
- have recently received or plan to receive an immunization (vaccine). You should not be given certain types of vaccines (called 'live vaccines') while using Omvoh.
- have liver problems.
- experience signs of an allergic reaction or other reaction to an infusion such as wheezing, difficulty breathing, hives, itching, swelling or dizziness. These could occur during or several hours after the infusion.

**Other warnings you should know about:**

Your healthcare professional may check blood tests while taking Omvoh to help tell if your liver is functioning normally. If blood tests are abnormal, your healthcare professional might interrupt therapy with Omvoh and do additional tests on your liver to determine the cause.

Omvoh is not approved for children and adolescents under 18 years of age. This is because it has not been studied in this age group.

If you are pregnant, think you may be pregnant or are planning to have a baby, ask your healthcare professional for advice before using this medicine. This is because it is not known if Omvoh can harm your unborn baby. If you are a woman of childbearing potential, use adequate contraception while using Omvoh. Talk to your healthcare professional about your contraception options.

If you are breastfeeding or are planning to breastfeed, talk to your healthcare professional before using this medicine. It is not known if Omvoh passes into breast milk. You and your healthcare professional should decide if you will breastfeed while using Omvoh.

**Tell your healthcare professional about all the medicines you take, including any drugs, vitamins, minerals, natural supplements or alternative medicines.**

Omvoh may change the way the body responds to live vaccines.

**How to take Omvoh:**

- You will first receive Omvoh through a vein in the arm (intravenous infusion or IV) given by a healthcare professional every 4 weeks for a total of 3 doses.
- Your healthcare professional may decide that you may benefit from an additional 3 doses of Omvoh by intravenous infusion.
- You will then continue to receive Omvoh as an injection under the skin (subcutaneous injection) every 4 weeks as described below.

**Treatment Start: Intravenous Infusion**

- Omvoh will be given to you by a healthcare professional in a healthcare setting.
- You will be given Omvoh through a needle placed in a vein (intravenous infusion or IV) in your arm over a period of about 30 minutes.
- Your healthcare professional will monitor you closely during the infusion.

**Maintenance Treatment: Subcutaneous Injection by prefilled pen or prefilled syringe**

- Use Omvoh exactly as your healthcare professional tells you to.
- Omvoh comes as 2 different types of devices:
  - a single-patient-use (1 time use only) prefilled pen
  - a single-patient-use (1 time use only) prefilled syringe
- Your healthcare professional will decide with you which type of device is best for you.
- For your full dose, you will need either 2 injections with the prefilled pen or 2 injections with the prefilled syringe. Inject 1 Omvoh pen or syringe followed right away by the other Omvoh pen or syringe.
- Omvoh is intended for use under the guidance and supervision of your healthcare professional. If your healthcare professional decides that you or a caregiver may give your injections of Omvoh at home, you should receive training on the correct way to prepare and inject Omvoh. Do not try to inject Omvoh yourself until you or your caregiver have been shown how to inject Omvoh.
- Omvoh can be injected by patients and/or caregivers under the skin in your stomach area (abdomen) or upper leg (thigh). Omvoh can be injected only by caregivers in the back of the upper arm.
- Use a different injection site each time you use Omvoh. For example, if the first injection was in the abdomen, the second injection - to complete a full dose - should be in another area of the abdomen, thigh, or back of upper arm. Rotate injection sites.
- Do not give an injection in an area that is tender, bruised, red, or hard.
- Do not use this medication if it looks cloudy or is leaking.
- **Read the detailed Instructions for Use that come with Omvoh prefilled pen or prefilled syringe about how to use Omvoh the correct way.**

#### Usual dose:

The recommended dosing schedule is as follows:

Treatment	Time of treatment	Dose and Route of administration
<b>Treatment Start</b>	Weeks 0, 4 and 8	300 mg intravenous infusion
If you do not have adequate therapeutic response after these 3 infusions, your healthcare professional might consider continuing intravenous infusions at weeks 12, 16 and 20.		
<b>Maintenance Treatment</b>	4 weeks after Treatment Start and then every 4 weeks thereafter	200 mg subcutaneous injection Given either as: • 2 injections of 100 mg prefilled pens, or • 2 injections of 100 mg prefilled syringes

#### Overdose:

If you think you, or a person you are caring for, have taken too much Omvoh, contact a healthcare professional, hospital emergency department, or regional poison control centre immediately, even if there are no symptoms.

#### Missed Dose:

Intravenous Infusion

- If you forget or miss an appointment to receive the Omvoh infusion, make another appointment as soon as possible.

#### Subcutaneous Injection

- If you miss a dose of Omvoh, inject the missed dose as soon as you remember. Then, take your next dose at your regularly scheduled time. If you have questions about your schedule, ask your healthcare professional.

#### What are possible side effects from using Omvoh?

These are not all the possible side effects you may have when taking Omvoh. If you experience any side effects not listed here, tell your healthcare professional.

#### The most common side effects of Omvoh include:

- Injection site reactions
- Upper respiratory infections
- Headache
- Joint pain
- Rash

Serious side effects and what to do about them			
Symptom / effect	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
<b>UNCOMMON</b>			
<b>Infection</b> Symptoms include: fever, chills, muscle aches, cough, shortness of breath, or pain during urination		X	
<b>RARE</b>			
<b>Serious allergic reactions</b> Symptoms include: fainting, dizziness, feeling lightheaded (low blood pressure); swelling of your face, eyelids, lips, mouth, tongue or throat; trouble breathing or throat tightening; chest tightness		X	X
Liver problems. Symptoms include tiredness, loss of appetite, pain on the right side of your stomach, dark urine, or yellowing of the skin and eyes (jaundice) or itching of the skin		X	

If you have a troublesome symptom or side effect that is not listed here or becomes bad enough

to interfere with your daily activities, tell your healthcare professional.

### **Reporting Side Effects**

You can report any suspected side effects associated with the use of health products to Health Canada by:

- Visiting the Web page on Adverse Reaction Reporting (<https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada.html>) for information on how to report online, by mail or by fax; or
- Calling toll-free at 1-866-234-2345.

*NOTE: Contact your health professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.*

### **Storage:**

- Store refrigerated at 2°C to 8°C.
- Do NOT freeze. Do not use Omvoh if it has been frozen.
- Do NOT shake.
- Keep Omvoh in the original carton to protect from light until the time of use.
- Throw away (dispose of) your prefilled pens or prefilled syringes, as described in the Instructions for Use, if any of the above conditions are not followed.
- If needed, your prefilled syringes or prefilled pens may be stored at room temperature up to 30°C for up to 2 weeks in the original carton to protect from light. Once Omvoh has been stored at room temperature, do not return it to the refrigerator and discard any unused Omvoh after 2 weeks.

**Keep Omvoh and all medicines out of the reach of children.**

### **If you want more information about Omvoh:**

- Talk to your healthcare professional.
- Find the full product monograph that is prepared for healthcare professionals and includes this Patient Medication Information by visiting the Health Canada website (<https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/drug-product-database.html>), the manufacturer's website ([www.lilly.ca](http://www.lilly.ca)), or by calling 1-888-545-5972.
- Instructions for Use can be found on [www.lilly.ca](http://www.lilly.ca)

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