

Medication Guide

OMVOH™ (ahm-VOH)
(mirikizumab-mrkz)

injection, for intravenous or subcutaneous use

What is the most important information I should know about OMVOH?

OMVOH can cause serious side effects, including:

- **Serious allergic reactions.** OMVOH may cause serious allergic reactions that may need to be treated in a hospital and may be life-threatening. Stop using OMVOH and get emergency medical help right away if you develop any of the following symptoms of a serious allergic reaction:
 - fainting, dizziness, feeling lightheaded (low blood pressure)
 - trouble breathing, throat tightening or wheezing
 - fast heartbeat or pounding in your chest (tachycardia)
 - swelling of your face, eyelids, lips, mouth, tongue, throat, or trouble swallowing
 - chest tightness
 - severe itching, hives, or redness all over your body
 - sweating
- **Infections.** OMVOH may lower the ability of your immune system to fight infections and may increase your risk of infections. Your healthcare provider should not start treatment with OMVOH until your infection is gone.
 - Before starting your treatment with OMVOH, your healthcare provider should test you for tuberculosis (TB).
 - If your healthcare provider feels that you are at risk for TB, you may be treated with medicine for TB before you begin treatment with OMVOH.
 - Your healthcare provider should watch you closely for signs and symptoms of TB while you are being treated with OMVOH and after treatment.
 - Before starting OMVOH, tell your healthcare provider if you think you have an infection or have symptoms of an infection such as:
 - fever, sweating, or chills
 - muscle aches and pain
 - cough or shortness of breath
 - blood in your mucus (phlegm)
 - flu-like symptoms
 - headache
 - warm, red, or painful skin or sores on your body
 - diarrhea or stomach pain
 - weight loss
 - nausea or vomiting
 - pain during urination

After starting OMVOH, tell your healthcare provider right away if you have any symptoms of an infection.
- **Liver problems.** OMVOH may cause liver problems. Your healthcare provider will do blood tests to check your liver enzyme and bilirubin levels before treatment, for at least 24 weeks during treatment, and possibly after treatment with OMVOH. Your healthcare provider may hold or stop your treatment if needed. Tell your healthcare provider right away if you develop any signs and symptoms of liver problems, including:
 - unexplained rash
 - nausea
 - vomiting
 - stomach-area (abdominal) pain
 - feeling tired
 - loss of appetite
 - yellowing of the skin or the whites of your eyes
 - dark urine

What is OMVOH?

OMVOH is a prescription medicine used in adults with moderately to severely active ulcerative colitis. It is not known if OMVOH is safe and effective in children.

Do not use OMVOH if you:

- are allergic to mirikizumab-mrkz or any of the ingredients in OMVOH. See the end of this Medication Guide for a complete list of ingredients in OMVOH.

Before you use OMVOH, tell your healthcare provider about all your medical conditions, including if you:

- have any of the conditions or symptoms listed in the section **“What is the most important information I should know about OMVOH?”**
- have recently received or are scheduled to receive any vaccinations. Medicines that affect your immune system may increase your risk of getting an infection after receiving live vaccines.
 - You should be brought up to date with all age required vaccines before starting treatment with OMVOH.
 - You should avoid receiving ‘live’ vaccines right before, during, or right after treatment with OMVOH. Tell your healthcare provider that you are taking OMVOH before receiving a vaccine.
- are pregnant, or plan to become pregnant. It is not known if OMVOH will harm your unborn baby. There will be a pregnancy registry to collect information about women who are exposed to OMVOH during pregnancy. If you become pregnant while taking OMVOH, you are encouraged to report your pregnancy to Eli Lilly and Company at 1-800-Lilly-Rx (1-800-545-5979).
- are breastfeeding or plan to breastfeed. It is not known if OMVOH passes into your breast milk. Talk to your healthcare provider about the best way to feed your baby while using OMVOH.

Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements.

How should I use OMVOH?

- Use OMVOH exactly as your healthcare provider tells you to.
- You will receive your first 3 doses of OMVOH through a vein in your arm (intravenous infusion) in a healthcare facility by a healthcare provider every 4 weeks. Each infusion will last about 30 minutes.
- After your intravenous infusions, you will continue to receive OMVOH as an injection under the skin (subcutaneous injection) every 4 weeks as described below.
- **See the detailed Instructions for Use that comes with OMVOH for information on how to prepare and inject a dose of OMVOH, and how to properly throw away (dispose of) a used OMVOH prefilled pen or prefilled syringe.**
- OMVOH comes as 2 different types of 1-time use devices:
 - a prefilled pen.
 - a prefilled syringe.
 Your healthcare provider will decide which type of device is best for you.
- For your full dose, you will need 2 injections either with 2 prefilled pens or 2 prefilled syringes. Inject 1 OMVOH prefilled pen or prefilled syringe followed right away by the other OMVOH prefilled pen or prefilled syringe.
- **Injecting OMVOH under your skin:**
 - OMVOH is intended for use under the guidance and supervision of your healthcare provider. If your healthcare provider 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.
 - Inject OMVOH under the skin in your stomach area (abdomen), upper legs (thighs), or back of the upper arms.
 - **Do not** give an injection in an area that is tender, bruised, red, or hard.
 - Use a different injection site each time you use OMVOH.
- If you miss a dose of OMVOH, inject the missed dose as soon as possible. Then take your next dose in 4 weeks. If you have questions about how often you should use OMVOH, talk to your healthcare provider.

What are the possible side effects of OMVOH?

OMVOH can cause serious side effects, including:

- See “**What is the most important information I should know about OMVOH?**”

The most common side effects of OMVOH include:

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| ◦ upper respiratory infections | ◦ joint pain | ◦ rash |
| ◦ injection site reaction | ◦ headache | ◦ herpes viral infections |

Tell your healthcare provider if you have any side effect that bothers you or that does not go away.

These are not all the possible side effects of OMVOH. For more information, ask your healthcare provider or pharmacist.

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

How should I store OMVOH?

- Store OMVOH prefilled pens and prefilled syringes in a refrigerator at 36°F to 46°F (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.
- After removing your prefilled pens or prefilled syringes from the refrigerator, they can be stored at room temperature up to 86°F (30°C) for up to 2 weeks in the original carton to protect from light.
 - When OMVOH has been stored at room temperature, **do not** return it to the refrigerator.
- Throw away (dispose of) your prefilled pens and prefilled syringes if they:
 - are frozen.
 - have been shaken.
 - have not been protected from light in the original carton.
 - are stored at room temperature more than 2 weeks.

Keep OMVOH and all medicines out of the reach of children.

General information about the safe and effective use of OMVOH.

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. Do not use OMVOH for a condition for which it was not prescribed. Do not give OMVOH to other people, even if they have the same symptoms that you have. It may harm them.

You can ask your pharmacist or healthcare provider for information about OMVOH that is written for health professionals.

What are the ingredients in OMVOH?

Active ingredient: mirikizumab-mrkz.

Inactive ingredients: anhydrous citric acid, polysorbate 80, sodium chloride, sodium citrate, and Water for Injection.

OMVOH prefilled pens and prefilled syringes are not made with dry natural rubber latex.

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For more information, go to www.OMVOH.com or call 1-800-545-5979.

This Medication Guide has been approved by the U.S. Food and Drug Administration.

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