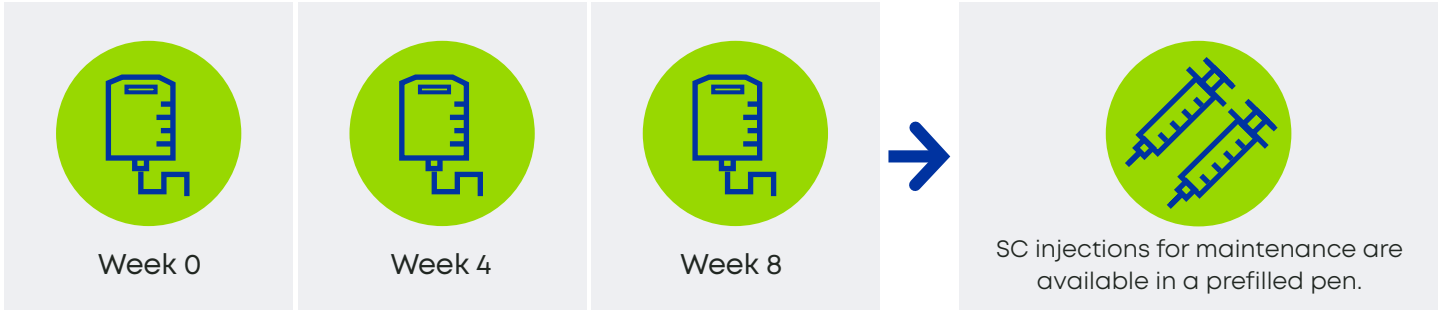
omvoh™
(mirikizumab-mrkz)
300 mg/15 mL infusion
100 mg/mL injection

DOSING AND ADMINISTRATION

Omvoh dosing begins with IV infusions and transitions to self-injections[1]

INDUCTION DOSING: 12 WEEKS[1]
IV infusions of 300 mg[a] at Weeks 0, 4, and 8

MAINTENANCE DOSING[1]
Two consecutive 100 mg SC injections (200 mg total) every 4 weeks starting at Week 12



[a]Over at least 30 minutes.[1]
Omvoh is intended for use under the guidance and supervision of a healthcare professional. Patients may self-inject after training in proper technique.[1]
IV=intravenous; SC=subcutaneous.

INDICATION
Omvoh is an interleukin-23 (IL-23) antagonist indicated for the treatment of moderately to severely active ulcerative colitis in adults.[1]

SELECT IMPORTANT SAFETY INFORMATION
Pretreatment Evaluations
Prior to initiating treatment with Omvoh, evaluate patients for tuberculosis infection, obtain liver enzymes and bilirubin levels, and complete all age-appropriate vaccinations according to current immunization guidelines.

Please click for Important Safety Information, Prescribing Information, and Medication Guide.
Please see Instructions for Use included with the device.

Lilly

ADMINISTRATION

Omvoh supply for IV infusion and SC injection[1]

For Intravenous Infusion	Strength	Pack Size
Single-dose Vial	300 mg/15 mL (20 mg/mL)	Carton of 1
For Subcutaneous Use	**Strength**	**Pack Size**
Single-use Prefilled Pen	100 mg/mL	Carton of 2

- Omvoh is a sterile, clear to opalescent, colorless to slightly yellow to slightly brown solution[1]

Storage and handling for IV infusion and SC injection[1]

- Store refrigerated at 2 °C to 8 °C (36 °F to 46 °F)
- Do not freeze. Do not use Omvoh if it has been frozen
- Keep Omvoh in the original carton to protect it from light until the time of use. Keep Omvoh away from direct heat or light
- Do not shake
- Discard any unused product

Storage of diluted solution for IV infusion[1]

It is recommended to start the infusion immediately after preparation. If that is not possible, store the diluted infusion solution in the refrigerator at 2 °C to 8 °C (36 °F to 46 °F).

- Use within 48 total hours, of which not more than 5 hours are permitted at non-refrigerated temperatures not to exceed 25 °C (77 °F), starting from the time of vial puncture
- Do not freeze the diluted solution in the prepared infusion bag

For SC injections[1]

The prefilled pen may be stored outside of refrigeration—if needed—at not more than 30 °C (86 °F) for up to 2 weeks in the original carton to protect it from light.

- Once Omvoh has been stored at room temperature, do not return it to the refrigerator. If these conditions are exceeded, Omvoh must be discarded

Omvoh IV infusion preparation[1]

To prepare Omvoh diluted solution for infusion:

- **Prepare the infusion solution using aseptic technique. Each vial is for single use only**
- **Visually inspect the contents of the vial. The solution should be clear to opalescent, colorless to slightly yellow to slightly brown, and free of visible particles. Do not use if the solution is cloudy or if there are visible particles**
- **Using an 18- to 21-gauge needle, withdraw 15 mL of Omvoh solution from the vial and transfer to the infusion bag ranging in size from 50 to 250 mL**
- **Omvoh should be diluted only in IV infusion bags containing EITHER 0.9% sodium chloride injection OR 5% dextrose injection. Do not mix with other drugs or dilute or infuse with other solutions**
- **Gently invert the infusion bag to mix the contents. Do not shake the prepared infusion bag**

OMVOH SOLUTION FOR IV INFUSION MUST BE

DILUTED + PREPARED + INFUSED

BY A HEALTHCARE PROFESSIONAL

Omvoh IV infusion administration instructions[1]

Connect the IV administration set (infusion line) to the prepared infusion bag and prime the line. Administer the infusion over at least 30 minutes.

- At the end of the infusion, flush the line with 0.9% sodium chloride injection or 5% dextrose injection
- Administer the flush at the same infusion rate as used for Omvoh administration
- The time required to flush the Omvoh solution from the infusion line is in addition to the minimum 30-minute infusion time

IV=intravenous; SC=subcutaneous.

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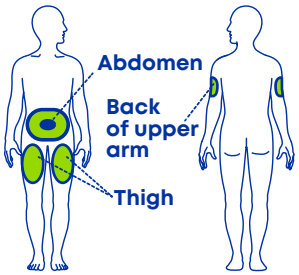
Omvoh SC injection administration instructions

PREFILLED PEN

Injection considerations include[1]:

- Omvoh is intended for use under the guidance and supervision of a healthcare professional (HCP)
- Patients may self-inject Omvoh after training in SC injection technique
- Provide proper training to patients and/or caregivers on the SC injection technique of Omvoh according to the "Instructions for Use" included with the packaged product



Approved injection sites are the abdomen, thigh, and back of the upper arm[1]

- Instruct patients to inject in a different location every time. 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, or upper arm, or thigh

Do not inject into areas where the skin is tender, bruised, erythematous, or indurated[1]

Before injection, remove the Omvoh prefilled pen from the refrigerator and leave at room temperature for 30 minutes[1]

Inspect Omvoh visually for particulate matter and discoloration prior to administration. Do not use Omvoh if it is cloudy or there are visible particles[1]

Omvoh does not contain preservatives; therefore, discard any unused product. **DO NOT REUSE**[1]

If a dose is missed, administer the dose as soon as possible. Thereafter, resume dosing every 4 weeks[1]

These are not the complete instructions for administering Omvoh. See Prescribing Information and Instructions for Use that come with the device[1]

INDICATION AND IMPORTANT SAFETY INFORMATION

INDICATION

Omvoh is an interleukin-23 (IL-23) antagonist indicated for the treatment of moderately to severely active ulcerative colitis in adults.[1]

CONTRAINDICATIONS - Omvoh is contraindicated in patients with a history of serious hypersensitivity reaction to mirikizumab-mrkz or any of the excipients.

WARNINGS AND PRECAUTIONS

Hypersensitivity Reactions

Serious hypersensitivity reactions, including anaphylaxis during intravenous infusion, have been reported with Omvoh administration. Infusion-related hypersensitivity reactions, including mucocutaneous erythema and pruritus, were reported during induction. If a severe hypersensitivity reaction occurs, discontinue Omvoh immediately and initiate appropriate treatment.

Infections

Omvoh may increase the risk of infection. Do not initiate treatment with Omvoh in patients with a clinically important active infection until the infection resolves or is adequately treated. In patients with a chronic infection or a history of recurrent infection, consider the risks and benefits prior to prescribing Omvoh. Instruct patients to seek medical advice if signs or symptoms of clinically important acute or chronic infection occur. If a serious infection develops or an infection is not responding to standard therapy, monitor the patient closely and do not administer Omvoh until the infection resolves.

Tuberculosis

Evaluate patients for tuberculosis (TB) infection prior to initiating treatment with Omvoh. Do not administer Omvoh to patients with active TB infection. Initiate treatment of latent TB prior to administering Omvoh. Consider anti-TB therapy prior to initiation of Omvoh in patients with a history of latent or active TB in whom an adequate course of treatment cannot be confirmed. Monitor patients for signs and symptoms of active TB during and after Omvoh treatment. In clinical trials, subjects were excluded if they had evidence of active TB, a history of active TB, or were diagnosed with latent TB at screening.

Hepatotoxicity

Drug-induced liver injury in conjunction with pruritus was reported in a clinical trial patient following a longer than recommended induction regimen. Omvoh was discontinued. Liver test abnormalities eventually returned to baseline. Evaluate liver enzymes and bilirubin at baseline and for at least 24 weeks of treatment. Monitor thereafter according to routine patient management. Consider other treatment options in patients with evidence of liver cirrhosis. Prompt investigation of the cause of liver enzyme elevation is recommended to identify potential cases of drug-induced liver injury. Interrupt treatment if drug-induced liver injury is suspected, until this diagnosis is excluded. Instruct patients to seek immediate medical attention if they experience symptoms suggestive of hepatic dysfunction.

Immunizations

Avoid use of live vaccines in patients treated with Omvoh. Medications that interact with the immune system may increase the risk of infection following administration of live vaccines. Prior to initiating therapy, complete all age-appropriate vaccinations according to current immunization guidelines. No data are available on the response to live or non-live vaccines in patients treated with Omvoh.

ADVERSE REACTIONS

Most common adverse reactions (≥2%) associated with Omvoh treatment are upper respiratory tract infections and arthralgia during induction, and upper respiratory tract infections, injection site reactions, arthralgia, rash, headache, and herpes viral infection during maintenance.

MR HCP ISI UC APP

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Reference: 1. Omvoh (mirikizumab-mrkz). Prescribing Information. Lilly USA, LLC.

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