For adults with moderate to severe UC or CD[1]

omvoh®
(mirikizumab-mrkz)

A Lilly Medicine

Hypothetical patients.

DOSING AND ADMINISTRATION

INDICATIONS

Ulcerative Colitis

Omvoh is indicated for the treatment of moderately to severely active ulcerative colitis (UC) in adults.

Crohn's Disease

Omvoh is indicated for the treatment of moderately to severely active Crohn's disease (CD) in adults.

SELECT IMPORTANT SAFETY INFORMATION: CONTRAINDICATIONS

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

Please click for additional Important Safety Information, Prescribing Information, and Medication Guide. Please see Instructions for Use for Pre-filled Pen for Ulcerative Colitis, Pre-filled Syringe for Ulcerative Colitis, Pre-filled Pen for Crohn's Disease, and Pre-filled Syringe for Crohn's Disease.

FOR ADULTS WITH MODERATE TO SEVERE UC OR CD[1]

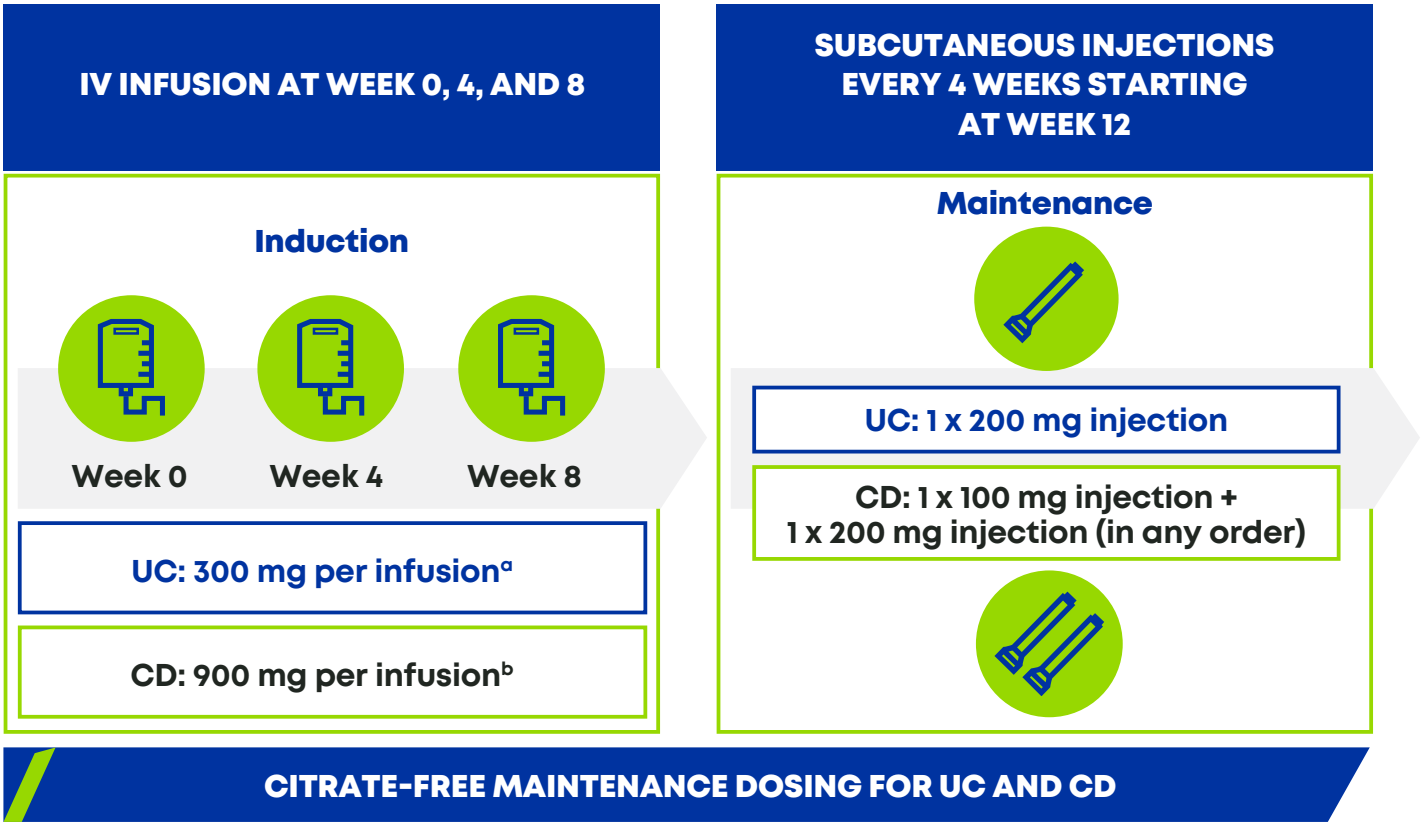
Dosing every 4 weeks, every time[1]

Omvoh dosing begins with IV infusions during induction and transitions to self-injections* for maintenance.[1]

Patients can take Omvoh with pens or prefilled syringes for maintenance dosing.[1]

*Omvoh is intended for use under the guidance and supervision of a healthcare professional. Patients and/or caregivers may inject after training in proper technique.[1]

OMVOH INDUCTION AND MAINTENANCE DOSING[1]



CITRATE-FREE MAINTENANCE DOSING FOR UC AND CD

[a]For at least 30 minutes.[1]
[b]For at least 90 minutes.[1]
CD=Crohn's disease; IV=intravenous; UC=ulcerative colitis.

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.[1]

Please click for additional Important Safety Information, Prescribing Information, and Medication Guide. Please see Instructions for Use for Pre-filled Pen for Ulcerative Colitis, Pre-filled Syringe for Ulcerative Colitis, Pre-filled Pen for Crohn's Disease, and Pre-filled Syringe for Crohn's Disease.

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FOR ADULTS WITH MODERATE TO SEVERE UC OR CD

Omvoh IV infusion for induction

Omvoh for IV infusion is intended for preparation and administration by a healthcare provider using aseptic technique[1]

Omvoh 300 mg/15 mL single-dose vial for IV infusion[1]

- Omvoh is a sterile, preservative-free, clear to opalescent, colorless to slightly yellow to slightly brown solution for intravenous infusion

Special precautions for storage[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
- Do not shake
- Keep Omvoh in the original carton to protect from light until the time of use
- Omvoh is sterile and preservative-free. Discard any unused portion
- The vial is not made with dry natural rubber latex

Preparation and administration of Omvoh for IV infusion for UC[1]

1. Each vial is for single use only. A full induction dose will require 1 vial of 300 mg/15 mL.
2. Parenteral drug products should be inspected visually for particulate matter and discoloration prior to administration, whenever solution and container permit. The solution should be a clear to opalescent, colorless to slightly yellow to slightly brown solution, and free of visible particles. Do not use Omvoh if it is cloudy or there are visible particles.
3. Using an 18- to 21-gauge needle, withdraw 15 mL of Omvoh solution from the vial and transfer to a 50 mL, 100 mL, or 250 mL infusion bag of 0.9% sodium chloride injection or 5% dextrose injection. Do not mix with other drugs. Do not dilute or infuse through the same intravenous line with solutions other than 0.9% sodium chloride or 5% dextrose Injection.
4. Gently invert the infusion bag to mix the contents. Do not shake the prepared infusion bag.
5. Connect the intravenous administration set (infusion line) to the prepared infusion bag and prime the line.
6. Administer the infusion over at least 30 minutes.
7. 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 Omvoh solution from the infusion line is in addition to the minimum 30-minute infusion time

Preparation and administration of Omvoh for IV infusion for CD[1]

1. Each vial is for single use only. A full 900 mg induction dose will require 3 vials of 300 mg/15 mL.
2. Parenteral drug products should be inspected visually for particulate matter and discoloration prior to administration, whenever solution and container permit. The solution should be a clear to opalescent, colorless to slightly yellow to slightly brown solution, and free of visible particles. Do not use Omvoh if it is cloudy or there are visible particles.
3. Using an 18- to 21-gauge needle, withdraw and discard 45 mL of solution from a 100 mL or 250 mL infusion bag containing 0.9% sodium chloride injection or 5% dextrose injection.
4. Using a separate 18- to 21-gauge needle, withdraw 15 mL of Omvoh solution from each of three vials (45 mL total) and transfer to the infusion bag. Do not mix with other drugs. Do not dilute or infuse through the same intravenous line with solutions other than 0.9% sodium chloride or 5% dextrose injection.
5. Gently invert the infusion bag to mix the contents. Do not shake the prepared infusion bag.
6. Connect the intravenous administration set (infusion line) to the prepared infusion bag and prime the line.
7. Administer the infusion over at least 90 minutes.
8. 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 Omvoh solution from the infusion line is in addition to the minimum 90-minute infusion time

Storage and handling of diluted solution for IV infusion[1]

- Start the infusion immediately after preparation. If not used immediately, store the diluted infusion solution in the refrigerator at 2°C to 8°C (36°F to 46°F). Use the diluted infusion solution 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
- If stored refrigerated, allow the diluted solution in the infusion bag to warm to room temperature prior to the start of the intravenous infusion
- Keep drug product away from direct heat or light. Do not freeze the diluted solution in the prepared infusion bag

Please click for Important Safety Information, Prescribing Information, and Medication Guide. Please see Instructions for Use for Pre-filled Pen for Ulcerative Colitis, Pre-filled Syringe for Ulcerative Colitis, Pre-filled Pen for Crohn's Disease, and Pre-filled Syringe for Crohn's Disease.

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FOR ADULTS WITH MODERATE TO SEVERE UC OR CD

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
- Inspect the content of the vial. The solution should be clear, colorless to slightly yellow to slightly brown and free of visible particles. Otherwise, it should be discarded
- **For CD:** Using an 18- to 21-gauge needle, withdraw and discard 45 mL of solution from a 100 mL or 250 mL infusion bag containing 0.9% sodium chloride injection or 5% dextrose injection

  Using a separate 18- to 21-gauge needle, withdraw 15 mL of Omvoh solution from each of the three vials (900 mg). Transfer to the infusion bag
- **For UC:** Using an 18- to 21-gauge needle, withdraw 15 mL of Omvoh solution from one vial (300 mg). Transfer to the infusion bag (ranging in size from 50 mL to 250 mL)
- Omvoh should be diluted only in IV infusion bags containing EITHER 0.9% sodium chloride Injection OR 5% dextrose injection
- Gently invert the infusion bag to mix. Do not shake the prepared bag

OMVOH SOLUTION FOR IV INFUSION MUST BE

DILUTED + PREPARED + INFUSED

BY A HEALTHCARE PROFESSIONAL

Omvoh IV infusion administration instructions[1]

After following instructions to prepare Omvoh for intravenous infusion, connect the IV administration set (infusion line) to the prepared infusion bag and prime the line. Administer the infusion over at least 30 minutes for UC and 90 minutes for CD.[1]

- 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 for UC and 90-minute infusion time for CD

OMVOH IV SUPPLY[1]

For Intravenous Infusion	Strength	Pack Size
Single-dose vial	300 mg/15 mL (20 mg/mL)	Carton of 1

Please click for Important Safety Information, Prescribing Information, and Medication Guide. Please see Instructions for Use for Pre-filled Pen for Ulcerative Colitis, Pre-filled Syringe for Ulcerative Colitis, Pre-filled Pen for Crohn's Disease, and Pre-filled Syringe for Crohn's Disease.

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FOR ADULTS WITH MODERATE TO SEVERE UC OR CD

Omvoh subcutaneous (SC) injection for maintenance

Prefilled pen and prefilled syringe storage and handling[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
- Do not shake
- Keep Omvoh in the original carton to protect from light until the time of use
- Omvoh is sterile and preservative-free. Discard any unused portion
- If needed, the prefilled pen or prefilled syringe may be stored at room temperature up to 30°C (86°F) for up to 2 weeks in the original carton to protect from light. Once Omvoh has been stored at room temperature, do not return to the refrigerator. If these conditions are exceeded, Omvoh must be discarded
- Prefilled pens and prefilled syringes are not made with dry natural rubber latex

Preparation and administration of Omvoh for SC injection for UC and CD[1]

1. Omvoh is intended for use under the guidance and supervision of a healthcare professional. After proper training in subcutaneous injection technique, a patient may self-inject Omvoh or a caregiver may administer the injection(s).
2. Before injection remove Omvoh prefilled pen(s) or prefilled syringe(s) from the refrigerator and leave at room temperature for 45 minutes. Refer to Omvoh dosing for UC and CD.
3. Instruct patients to visually inspect Omvoh prior to administration. The solution should be a clear to opalescent, colorless to slightly yellow to slightly brown solution. Do not use the medicine if it is cloudy, discolored, has particles, is damaged, or the expiry date printed on the label has passed.
4. Sites for injection include the abdomen, front of the thigh, and back of the upper arm. Instruct patients to inject in a different location every time. For example, if the first injection was in the abdomen, administer the second injection (to complete a full dose for CD) in another area of the abdomen, back of upper arm, or thigh. Do not inject within 2 inches of the belly button (navel). Administration of Omvoh in the back of upper arm may only be performed by another person.
5. Instruct patients not to inject into areas where the skin is tender, bruised, red, or hard.
6. Instruct patients not to reuse the prefilled pen or prefilled syringe. Each one is for one-time use only.
7. In case of a missed dose, instruct patients to inject as soon as possible. Thereafter, resume dosing every 4 weeks.

OMVOH SUPPLY FOR UC[1]

For Subcutaneous Use	Strength	Pack Size
Single-dose prefilled pen or prefilled syringe	200 mg/2 mL	Carton of 1

OMVOH SUPPLY FOR CD[1]

For Subcutaneous Use	Strengths	Pack Size
Single-dose prefilled pens	200 mg/2 mL + 100 mg/mL	Carton of 2 (1 of each)
Single-dose prefilled syringes	200 mg/2 mL + 100 mg/mL	Carton of 2 (1 of each)

CD=Crohn's disease; IV=intravenous; UC=ulcerative colitis.

SELECT IMPORTANT SAFETY INFORMATION: 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.

Please click for additional Important Safety Information, Prescribing Information, and Medication Guide. Please see Instructions for Use for Pre-filled Pen for Ulcerative Colitis, Pre-filled Syringe for Ulcerative Colitis, Pre-filled Pen for Crohn's Disease, and Pre-filled Syringe for Crohn's Disease.

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FOR ADULTS WITH MODERATE TO SEVERE UC OR CD

Omvoh SC injection administration instructions

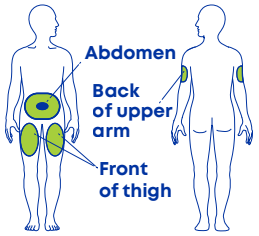
Prefilled Pen or Prefilled Syringe

Important information to know before injecting Omvoh[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 devices

INJECTION SITES FOR OMVOH[1-3]

Approved injection sites are the abdomen at least two inches from the navel, front of the thigh, and back of the upper arm. Do not inject within 2 inches of belly button (navel). 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, upper arm, or front of the thigh. Administration of Omvoh in the back of upper arm may only be performed by another person[1-3]



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

Before injection, remove Omvoh from the refrigerator and leave at room temperature for 45 minutes

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.

SELECT IMPORTANT SAFETY INFORMATION: 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.

Please click for additional Important Safety Information, Prescribing Information, and Medication Guide. Please see Instructions for Use for Pre-filled Pen for Ulcerative Colitis, Pre-filled Syringe for Ulcerative Colitis, Pre-filled Pen for Crohn's Disease, and Pre-filled Syringe for Crohn's Disease.

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OMVOH SAVINGS PROGRAM: MAKING TREATMENT MORE AFFORDABLE

$5
per treatment*

If your patients have **commercial drug insurance that covers Omvoh**, they may be eligible to pay as little as $5 per treatment.

$0
per treatment*

If your patients have **commercial drug insurance that does not cover Omvoh**, they may be eligible to pay as little as $0 per treatment.

*Treatment is defined as one infusion or one 28-day supply of subcutaneous injections.

TERMS AND CONDITIONS

Governmental beneficiaries excluded. Eligibility required, terms and conditions apply. Savings subject to monthly and annual limits. Month is defined as 28-days. Card eligibility and terms and conditions may be terminated, rescinded, revoked, or amended by Lilly at any time without notice and for any reason. **PROGRAM IS NOT INSURANCE.** Review full terms and conditions at https://omvoh.lilly.com/hcp/savings-support#hcpTermsAndConditionsAccordion.

Please click for additional Important Safety Information, Prescribing Information, and Medication Guide. Please see Instructions for Use for Pre-filled Pen for Ulcerative Colitis, Pre-filled Syringe for Ulcerative Colitis, Pre-filled Pen for Crohn's Disease, and Pre-filled Syringe for Crohn's Disease.

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IMPORTANT SAFETY INFORMATION

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 subject 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 associated with Omvoh (≥2% of subjects and at a higher frequency than placebo) in ulcerative colitis treatment are upper respiratory tract infections and arthralgia during the induction study (UC-1), and upper respiratory tract infections, injection site reactions, arthralgia, rash, headache, and herpes viral infection during the maintenance study (UC-2).

Most common adverse reactions associated with Omvoh in the Crohn's disease study (CD-1) (≥5% of subjects and at a higher frequency than placebo) are upper respiratory tract infections, injection site reactions, headache, arthralgia, and elevated liver tests.

Omvoh injection is available as a 300 mg/15 mL solution in a single-dose vial for intravenous infusion, and as a 100 mg/mL solution or a 200 mg/2 mL solution in a single dose prefilled pen or prefilled syringe for subcutaneous injection. Refer to the Prescribing Information for dosing information.

MR HCP ISI CD APP

Please click for Prescribing Information, and Medication Guide. Please see Instructions for Use for Pre-filled Pen for Ulcerative Colitis, Pre-filled Syringe for Ulcerative Colitis, Pre-filled Pen for Crohn's Disease, and Pre-filled Syringe for Crohn's Disease.

References: 1. Omvoh. Prescribing Information. Lilly USA, LLC. **2.** Omvoh. Prefilled Pen Instructions for Use. Lilly USA, LLC. **3.** Omvoh. Prefilled Syringe Instructions for Use. Lilly USA, LLC.

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