## Crohn's Disease (CD)

# ePRESCRIPTION (eRx) INSTRUCTIONS FOR gGASTRO® ELECTRONIC HEALTH RECORD (EHR) SYSTEM

omvoh® (mirikizumab-mrkz)

A Lilly Medicine

## BACKGROUND, INSTRUCTIONS, AND LIMITATIONS

These instructions were created specifically to complete an Omvoh eRx in the gGastro EHR system and will not work in other EHR systems. These instructions are designed to be used with Omvoh for its FDA-approved CD indication and should not be used for other conditions, treatments, or therapeutic areas.

The processes outlined in this resource are variable and not all steps will apply to every customer. Any steps or settings that are not part of a customer's standard process should be excluded or modified accordingly. Any questions should be directed to the appropriate service provider. The customer is solely responsible for implementing, testing, monitoring, and the ongoing operation of any EHR resource.

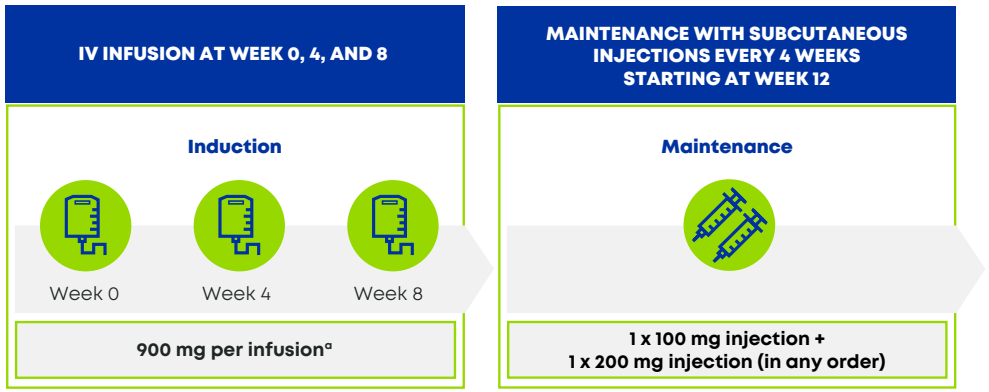
Treatment selection is always a decision made by the healthcare professional (HCP). An EHR newsletter or other communication medium may be considered to notify end users of the Omvoh medication details to consider when completing an eRx in the EHR.

For adults with moderately to severely active CD

## INDICATION-SPECIFIC DOSING

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

Patients can take Omvoh via prefilled pens or prefilled syringes for maintenance dosing.




Omvoh for IV infusion is supplied as a single-dose vial with a strength of 300 mg/15 mL (20 mg/mL) and packaged in a carton of 1.

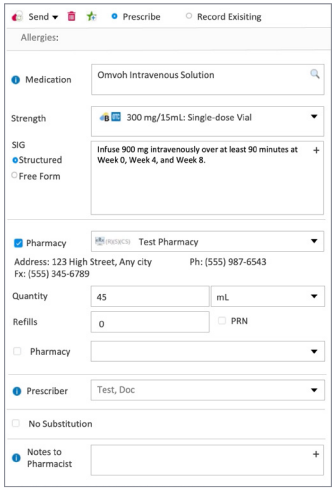
Omvoh for SC use is supplied as single-dose prefilled pens with strengths of 100 mg/mL and 200 mg/2 mL, packaged in a carton of 2 (1 of each), or prefilled syringes with strengths of 100 mg/mL and 200 mg/2 mL, packaged in a carton of 2 (1 of each). The total dispensing quantity is 3 mL.

Omvoh is intended for use under the guidance and supervision of an HCP. Patients may self-inject after training in proper technique.

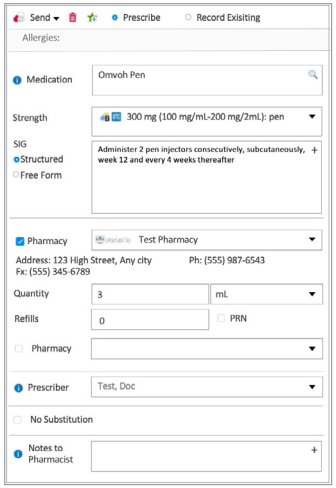
[a]For at least 90 minutes.

FDA=U.S. Food and Drug Administration; IV=intravenous; SC=subcutaneous

Example of Omvoh **Induction** Medication Details for Moderately to Severely Active CD in Adults




Example of Omvoh **Maintenance** Medication Details for Moderately to Severely Active CD in Adults




Note: These are **example** medication details. Individual practice selections may vary. Complete the **Notes to Pharmacist** field with any additional details your practice may desire.

## INDICATION

Omvoh is an interleukin-23 antagonist indicated for adults with moderately to severely active Crohn's disease.

## 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.

**Please see additional Important Safety Information on the next page, and see Prescribing Information and Medication Guide for Omvoh. Please see Instructions for Use included with the device.**

## gGASTRO INSTRUCTIONS FOR CD

Completing an eRx for Omvoh requires minimal time.

1. From a **patient's chart,** navigate to the **Plan** section.
2. In the panel on the right, select the **Search** tab.
3. In the second field, **Medication,** enter **Omvoh**.
4. All Omvoh formulations will be listed: Omvoh 300 mg/15 mL (20 mg/mL) IV solution, Omvoh 100 mg/mL single-dose prefilled pen or single-dose prefilled syringe for SC use, and Omvoh 200 mg/2 mL + 100 mg/mL single-dose prefilled pen or single-dose prefilled syringe for SC use.
5. **Select the desired Omvoh formulation** from the list to **complete the medication details:**

   a. **Induction dosing:** The recommended induction dose for adult patients with moderately to severely active CD for Omvoh is 900 mg administered by IV infusion over at least 90 minutes at Week 0, Week 4, and Week 8. Omvoh for IV infusion is supplied as a single-dose vial with a strength of 300 mg/15 mL (20 mg/mL) and packaged in a carton of 1.

   In the structured text sig, enter: Infuse 900 mg intravenously, over at least 90 minutes at Week 0, Week 4, and Week 8.

   *When the standard drop-down options to complete the sig field do not contain all of the details needed to complete the sig, consider adding the information above to represent the full details. The text may be abbreviated as desired.*

   Additional settings may be adjusted per health system preference (e.g., consider the Omvoh recommended evaluations and immunizations prior to treatment initiation. See section 2.1 in the Prescribing Information).

   Information regarding preparation and administration of Omvoh for IV infusion can be found in section 2.5 of the Prescribing Information.

   b. **Maintenance dosing:** The recommended maintenance dose for adult patients with moderately to severely active CD for Omvoh is 300 mg administered by SC injection (given as 2 consecutive injections of 100 mg and 200 mg in any order, 1 of each, in different injection sites. Sites for injection can include the abdomen, back upper arm, or front of thigh.) at Week 12 and every 4 weeks thereafter. Omvoh for SC use is supplied as a single-dose prefilled pen or prefilled syringe with a strength of 100 mg/mL and 200 mg/2 mL and packaged in a carton of 2 (1 of each) for a total dispensing quantity of 3 mL.

   In the structured text sig, enter: Administer 2 pen injectors consecutively, subcutaneously, week 12 and every 4 weeks thereafter.

   *When the standard drop-down options to complete the sig field do not contain all of the details needed to complete the sig, consider adding the information above to represent the full details. The text may be abbreviated as desired.*

   Additional settings may be adjusted per health system preference (e.g., there are recommended evaluations and immunizations prior to initiating treatment with Omvoh. See section 2.1 in the Prescribing Information).

   Information regarding preparation and administration of Omvoh for SC injection can be found in section 2.6 of the Prescribing Information.

6. Click **Send** once all the medication details and pharmacy selection have been completed.

### NOTES

- The customers (i.e., physician, medical group, integrated delivery network) shall be solely responsible for implementation, testing, and monitoring of the instructions to ensure proper orientation in each customer's EHR system
- Capabilities, functionality, and set-up (customization) for each EHR system may vary. Eli Lilly and Company shall not be responsible for revising the implementation instructions it provides to any customer if the customer modifies or changes their software, or the configuration of their EHR system, after such time as the implementation instructions have been initially provided by Lilly
- While Lilly tests its implementation instructions on multiple EHR systems, the instructions are not guaranteed to work for all available EHR systems and Lilly shall have no liability thereto
- The instructions have not been designed to and are not resources and/or solutions for meeting Advancing Care Information and/or any other quality/accreditation requirement
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## IMPORTANT SAFETY INFORMATION (CONT.)

### WARNINGS AND PRECAUTIONS (CONT.)

#### 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 see Prescribing Information and Medication Guide for Omvoh. Please see Instructions for Use included with the device.**

**Reference:** Omvoh. Prescribing Information. Lilly USA, LLC.



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omvoh®
(mirikizumab-mrkz)