

OMVOH (mirikizumab-mrkz)

Provider Order Form

Date: _____

INDICATIONS AND USAGE OMVOHTM is an interleukin-23 antagonist indicated for the treatment of moderately to severely active ulcerative colitis in adults (1) DOSAGE AND ADMINISTRATION <u>Prior to Treatment Initiation</u> - Evaluate patients for tuberculosis (TB) infection. (2.1, 5.3) - Obtain liver enzymes and bilirubin levels. (2.1, 5.4) - Complete all age-appropriate vaccinations according to current <u>Recommended Dosage</u> <u>Recommended Dosage</u> - The recommended induction dosage is 300 mg administered by intravenous infusion over at least 30 minutes at Weeks 0, 4, and 8. (2.2) - The recommended maintenance dosage is 200 mg administered by subcutaneous injection (given as two consecutive injections of 100 mg each) at Week 12, and every 4 weeks thereafter. (2.2) <u>Preparation and Administration</u> - See the full prescribing information for preparation, administration and storage information for intravenous infusion and subcutaneous injection. (2.3, 2.4) DOSAGE FORMS AND STRENGTH Intravenous Infusion (3) - Injection: 300 mg/15 mL (20 mg/mL) solution in a single-dose vial Subcutaneous Injection (3): - Injection: 100 mg/mL solution in a single-dose prefilled pen CONTRAINDICATIONS History of serious hypersensitivity reaction to mirikizumab-mrkz or any of the excipients. (4, 5.1). WARNINGS AND PRECAUTIONS <u>Hypersensitivity Reactions</u>: Serious hypersensitivity reactions, including anaphylaxis and infusion-related reactions, have been reported. If a severe hypersensitivity reaction occurs, discontinue and initiate appropriate treatment. (5.1) <u>Infections</u>: 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. If a serious infection develops, do not administer OMVOH until the infection resolves. (5.2) <u>Tuberculosis</u>: Do not administer OMVOH to patients with active TB infection. Monitor patients receiving OMVOH for signs and symptoms of active TB during and after treatment. (5.3) <u>Hepatotoxicity</u>: Drug-induced liver injury has been reported. Monitor liver enzymes and bilirubin levels at baseline and for at	least 24 weeks of treatment and thereafter according to routine patient management. Interrupt treatment if drug-induced liver injury is suspected, until this diagnosis is excluded. (5.4) <u>Immunizations</u>: Avoid use of live vaccines. (5.5) ADVERSE REACTIONS Most common adverse reactions (≥2%) are: - Induction: upper respiratory tract infections and arthralgia. (6.1) - Maintenance: upper respiratory tract infections, injection site reactions, arthralgia, rash, headache, and herpes viral infection. (6.1) FULL PRESCRIBING INFORMATION: CONTENTS* 1 INDICATIONS AND USAGE 2 DOSAGE AND ADMINISTRATION 2.1 Recommended Evaluations and Immunizations Prior to Treatment Initiation 2.2 Recommended Dosage 2.3 Preparation and Administration of OMVOH for Intravenous Infusion 2.4 Preparation and Administration of OMVOH for Subcutaneous Injection 3 DOSAGE FORMS AND STRENGTHS 4 CONTRAINDICATIONS 5 WARNINGS AND PRECAUTIONS 5.1 Hypersensitivity Reactions 5.2 Infections 5.3 Tuberculosis 5.4 Hepatotoxicity 5.5 Immunizations 6 ADVERSE REACTIONS 6.1 Clinical Trials Experience 8 USE IN SPECIFIC POPULATIONS 8.1 Pregnancy 8.2 Lactation 8.4 Pediatric Use 8.5 Geriatric Use 11 DESCRIPTION 12 CLINICAL PHARMACOLOGY 12.1 Mechanism of Action 12.2 Pharmacodynamics 12.3 Pharmacokinetics 12.6 Immunogenicity 13 NONCLINICAL TOXICOLOGY 13.1 Carcinogenesis, Mutagenesis, Impairment of Fertility 14 CLINICAL STUDIES 16 HOW SUPPLIED/STORAGE AND HANDLING 17 PATIENT COUNSELING INFORMATION * Sections or subsections omitted from the full prescribing information are not listed.
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