

Package leaflet: Information for the patient

Omvo^h® 200 mg solution for injection in pre-filled pen

mirikizumab

▼ This medicine is subject to additional monitoring. This will allow quick identification of new safety information. You can help by reporting any side effects you may get. See the end of section 4 for how to report side effects.

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, pharmacist or nurse.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Omvo^h is and what it is used for
2. What you need to know before you use Omvo^h
3. How to use Omvo^h
4. Possible side effects
5. How to store Omvo^h
6. Contents of the pack and other information

1. What Omvo^h is and what it is used for

Omvo^h contains the active substance mirikizumab, a monoclonal antibody. Monoclonal antibodies are proteins that recognise and bind specifically to certain target proteins in the body. Omvo^h works by attaching to and blocking a protein in the body called IL-23 (interleukin-23), which is involved in inflammation. By blocking the action of IL-23, Omvo^h reduces inflammation and other symptoms associated with ulcerative colitis.

Ulcerative colitis

Ulcerative colitis is a chronic inflammatory disease of the large bowel. If you have ulcerative colitis, you will first be given other medicines. If you do not respond well enough or cannot tolerate these medicines, you may be given Omvo^h to reduce signs and symptoms of ulcerative colitis such as diarrhoea, abdominal pain, urgency and rectal bleeding.

2. What you need to know before you use Omvo^h

Do not use Omvo^h

- if you are allergic to mirikizumab or any of the other ingredients of this medicine (listed in section 6). If you think you may be allergic, ask your doctor for advice before using Omvo^h.
- If you have important active infections (active tuberculosis).

Warnings and precautions

- Talk to your doctor or pharmacist before using this medicine.
- Your doctor will check how well you are before treatment.
- Make sure you tell your doctor about any illness you have before treatment.

Infections

- Omvoh can potentially cause serious infections. Treatment with Omvoh should not be started if you have an active infection until the infection is gone.
- After starting the treatment, tell your doctor right away if you have any symptoms of an infection such as:
 - fever
 - chills
 - muscle aches
 - cough
 - shortness of breath
 - runny nose
 - sore throat
 - pain during urination
- Also tell your doctor if you have recently been near anyone who might have tuberculosis.
- Your doctor will examine you and may do a test for tuberculosis before you have Omvoh.
- If your doctor thinks you are at risk of an active tuberculosis, you may be given medicines to treat it.

Vaccinations

Your doctor will check to see if you need any vaccinations before starting treatment. Tell your doctor, pharmacist or nurse if you have recently had or are going to have a vaccination. Some types of vaccines (live vaccines) should not be given while using Omvoh.

Allergic reactions

- Omvoh can potentially cause serious allergic reactions.
- Stop using Omvoh and get emergency medical help right away if you develop any of the following symptoms of a serious allergic reaction:
 - rash
 - fainting
 - dizziness
 - low blood pressure
 - swelling of the face, lips, mouth, tongue or throat, trouble breathing
 - sensation of throat tightening or chest tightness.

Liver blood test

Your doctor will conduct blood tests before starting and during treatment with Omvoh to check if your liver is functioning normally. If blood tests are abnormal, your doctor might interrupt therapy with Omvoh and do additional tests on your liver to determine the cause.

Children and adolescents

Omvoh is not recommended for children and adolescents under 18 years of age because it has not been studied in this age group.

Other medicines and Omvoh

Tell your doctor, pharmacist or nurse

- if you are using, have recently used or might use any other medicines.
- if you have recently had or are going to have a vaccination. Some types of vaccines (live vaccines) should not be given while using Omvoh.

Pregnancy and breast-feeding

If you are pregnant, think you may be pregnant, or are planning to have a baby, ask your doctor for advice before using this medicine. It is preferable to avoid the use of Omvoh in pregnancy. The

effects of Omvoh in pregnant women are not known. If you are a woman of childbearing potential, you are advised to avoid becoming pregnant and should use effective contraception while using Omvoh and for at least 10 weeks after the last Omvoh dose.

If you are breast-feeding or are planning to breast-feed, talk to your doctor before using this medicine.

Driving and using machines

Omvoh is unlikely to influence your ability to drive and use machines.

Omvoh contains sodium

This medicine contains less than 1 mmol sodium (23 mg) per dose, that is to say essentially “sodium -free”.

Omvoh contains polysorbate

This medicine contains 0.3 mg/mL of polysorbate 80 in each pen which is equivalent to 0.6 mg for the maintenance dose to treat ulcerative colitis. Polysorbates may cause allergic reactions. Tell your doctor if you have any known allergies.

3. How to use Omvoh

Always use this medicine exactly as your doctor or nurse has told you. Check with your doctor, nurse or pharmacist if you are not sure how to use this medicine.

How much Omvoh is given and for how long

Your doctor will decide how much Omvoh you need and for how long. Omvoh is for long-term treatment. Your doctor or nurse will regularly monitor your condition to check that the treatment is having the desired effect.

Ulcerative colitis

- **Treatment start:** The first dose of Omvoh is 300 mg and will be given by your doctor by intravenous infusion (drip in a vein in your arm) over at least 30 minutes. After the first dose, you will receive another dose of Omvoh 300 mg 4 weeks later and again after an additional 4 weeks.
If you do not have adequate therapeutic response after these 3 infusions, your doctor might consider continuing intravenous infusions at weeks 12, 16 and 20.
- **Maintenance therapy:** 4 weeks after the last intravenous infusion, a maintenance dose of Omvoh 200 mg will be given by an injection under the skin (‘subcutaneously’) and then every 4 weeks. The maintenance dose of 200 mg will be given by using 1 injection containing 200 mg of Omvoh.
If you lose response after receiving the maintenance dose of Omvoh, your doctor may decide to give you 3 doses of Omvoh by intravenous infusions.

Your doctor or nurse will tell you when to switch to subcutaneous injections.

During maintenance therapy you and your doctor or nurse should decide if you should inject Omvoh yourself after training in subcutaneous injection technique. It is important not to try to inject yourself until you have been trained by your doctor or nurse. Your doctor or nurse will offer the necessary training.

A caregiver may also give you your Omvoh injection after proper training.

Use a reminder method such as notes in a calendar or diary to help you remember when to take your next dose so that you avoid missing or repeating doses.

If you receive more Omvoh than you should

If you have received more Omvoh than you should or the dose has been given sooner than prescribed, inform your doctor.

If you forget to use Omvoh

If you have forgotten to inject a dose of Omvoh, inject as soon as possible. Thereafter, resume dosing every 4 weeks.

If you stop using Omvoh

You should not stop using Omvoh without speaking to your doctor first. If you stop treatment, symptoms of ulcerative colitis may come back.

If you have any further questions on the use of this medicine, ask your doctor, pharmacist or nurse.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Very common (may affect more than 1 in 10 people)

- Injection site reactions (e.g. red skin, pain)

Common (may affect up to 1 in 10 people):

- Upper respiratory tract infections (nose and throat infections)
- Joint pain
- Headache
- Rash

Uncommon (may affect up to 1 in 100 people):

- Shingles
- Infusion-related allergic reaction (e.g. itch, hives)
- Increase in the level of liver enzymes in your blood.

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme, website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects, you can help provide more information on the safety of this medicine.

5. How to store Omvoh

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the label and on the outer carton after "EXP". The expiry date refers to the last day of that month.

Store in a refrigerator (2 °C - 8 °C). Do not freeze.

Do not microwave the pen, run hot water over it, or leave it in direct sunlight.

Do not shake your pre-filled pen.

Store in the original packaging in order to protect from light.

OmvoH may be stored unrefrigerated for up to 2 weeks at a temperature not above 30 °C. If these conditions are exceeded, OmvoH must be discarded.

Do not use this medicine if you notice that the pre-filled pen is damaged, or the medicine is cloudy, distinctly brown, or has particles in it.

This medicine is for single use only.

Do not throw away any medicines via wastewater. Ask your doctor, nurse or pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What OmvoH contains

- The active substance is mirikizumab.
Each pre-filled pen contains 200 mg of mirikizumab in 2 mL solution.
- The other ingredients are histidine; histidine monohydrochloride; sodium chloride; mannitol (E 421); polysorbate 80 (E 433); water for injections.

What OmvoH looks like and contents of the pack

OmvoH is a solution in a clear glass cartridge encased in a disposable, single-use pen. Its colour may vary from colourless to slightly yellow.

OmvoH is available in packs containing 1 pre-filled pen of 200 mg and in multipacks comprising 3 cartons, each containing 1 pre-filled pen of 200 mg.
Not all pack sizes may be marketed.

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