

Package leaflet: Information for the patient

Entyvio 108 mg solution for injection in pre-filled pen vedolizumab

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

1. What Entyvio is and what it is used for

What Entyvio is

Entyvio contains the active substance ‘vedolizumab’. Vedolizumab belongs to a group of biological medicines called monoclonal antibodies (MAbs).

How Entyvio works

Entyvio works by blocking a protein on the surface of white blood cells that cause the inflammation in ulcerative colitis and Crohn’s disease. This reduces the amount of inflammation.

What Entyvio is used for

Entyvio is used to treat the signs and symptoms in adults of:

- moderately to severely active ulcerative colitis
- moderately to severely active Crohn’s disease.

Ulcerative colitis

Ulcerative colitis is a disease that causes inflammation 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, your doctor may give you Entyvio to reduce the signs and symptoms of your disease.

Crohn’s disease

Crohn’s disease is a disease that causes inflammation of the digestive system. If you have Crohn’s disease you will first be given other medicines. If you do not respond well enough or cannot tolerate these medicines, your doctor may give you Entyvio to reduce the signs and symptoms of your disease.

2. What you need to know before you use Entyvio

Do not use Entyvio

- if you are allergic to vedolizumab or any of the other ingredients of this medicine (listed in section 6).
- if you have an active severe infection - such as TB (tuberculosis), blood poisoning, severe diarrhoea and vomiting (gastroenteritis), nervous system infection.

Warnings and precautions

Talk to your doctor, pharmacist or nurse before using Entyvio.

Tell your doctor, pharmacist or nurse immediately when you first use this medicine, during treatment, and between doses:

- if you experience blurred, loss of or double vision, difficulty speaking, weakness in an arm or a leg, a change in the way you walk or problems with your balance, persistent numbness, decreased sensation or loss of sensation, memory loss or confusion. These may all be symptoms of a **serious and potentially fatal brain condition** known as progressive multifocal leukoencephalopathy (**PML**).
- if you have an **infection**, or think you have an infection – signs include chills, shivering, persistent cough or a high fever. Some infections may become serious and possibly even life-threatening if left untreated.
- if you experience signs of **an allergic reaction** such as wheezing, difficulty breathing, hives, itching, swelling or dizziness. For more detailed information, see allergic reactions in section 4.
- if you are going to receive any **vaccination** or have recently had a vaccination. Entyvio may affect the way you respond to a vaccination.
- if you have cancer, tell your doctor. Your doctor will have to decide if you can still be given Entyvio.
- if you are not feeling any better as vedolizumab may take up to 14 weeks to work in some patients with very active Crohn's disease.

Children and adolescents

Entyvio is not recommended for use in children or adolescents (under 18 years of age) due to the lack of information regarding the use of this medicine in this age group.

Other medicines and Entyvio

Tell your doctor, pharmacist or nurse if you are taking, have recently taken or might take any other medicines.

- Entyvio should not be given with other biologic medicines that suppress your immune system as the effect of this is not known.

Tell your doctor if you have previously taken:

- natalizumab (a medicine for multiple sclerosis) or
- rituximab (a medicine for certain types of cancer and rheumatoid arthritis).

Your doctor will decide if you can be given Entyvio.

Pregnancy and breast-feeding

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor for advice before taking this medicine.

Pregnancy

The effects of Entyvio in pregnant women are not known. Therefore, this medicine is not recommended for use during pregnancy. You and your doctor should decide if the benefit to you clearly outweighs the potential risk to yourself and your baby.

If you are a woman of childbearing potential, you are advised to avoid becoming pregnant while using Entyvio. You should use adequate contraception during treatment and for at least 4.5 months after the last treatment.

Breast-feeding

Tell your doctor if you are breast-feeding or planning to breast-feed. Entyvio passes into breast milk. There is not enough information on what effect this may have on your baby and on milk production. A decision must be made whether to stop breast-feeding or to stop using Entyvio therapy taking into account the benefit of breast-feeding for your child and the benefit of therapy for you.

Driving and using machines

This medicine has a minor effect on your ability to drive or use tools or machines. A small number of patients have felt dizzy after receiving Entyvio. If you feel dizzy, do not drive or use tools or machines.

Entyvio 108 mg solution for injection contains sodium

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

3. How to use Entyvio

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

You or your caregiver will be given training on how to use Entyvio subcutaneous injections.

How much Entyvio you will receive

Treatment with Entyvio is the same for ulcerative colitis and Crohn's disease.

The recommended dose is 108 mg of Entyvio administered by subcutaneous injection once every 2 weeks.

- At the start of treatment, the doctor will give initial doses of Entyvio through a drip into a vein in your arm (intravenous infusion) over about 30 minutes.
- After at least 2 intravenous infusions, you can start receiving Entyvio by an injection under the skin (subcutaneous injection). The first injection under the skin is given at the time of the next scheduled intravenous infusion, and every 2 weeks thereafter.

Injecting Entyvio

The subcutaneous injections can be given by yourself or a caregiver, after training on how to do it. Instructions are provided at the end of this leaflet.

If you forget to take or miss your Entyvio injection

If you forget or miss a dose, inject the next dose as soon as possible and then every 2 weeks thereafter.

If you stop using Entyvio

Do not stop using Entyvio without talking with your doctor first.

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.

Serious side effects

Tell your doctor **immediately** if you notice any of the following:

- allergic reactions (may affect up to 1 in 100 people) - the signs may include: wheezing or difficulty breathing, hives, itching of the skin, swelling, feeling sick, redness of skin and
- infections (may affect up to 1 in 10 people) - the signs may include: chills or shivering, high fever or rash

Other side effects

Tell your doctor **as soon as possible** if you notice any of the following:

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

- common cold
- joint pain
- headache

Common side effects (may affect up to 1 in 10 people)

- pneumonia
- infection of the large intestine due to *Clostridium difficile* bacteria
- fever
- chest infection
- changes in how your liver works, increase in liver enzymes (shown in blood tests)
- tiredness
- cough
- flu (influenza)
- back pain
- throat pain
- sinus infection
- itching / itchiness
- rash and redness
- pain in the limb
- muscle cramps
- muscle weakness
- throat infection
- stomach flu
- anal infection
- anal sore
- hard faeces
- bloated stomach
- passing gas
- high blood pressure
- prickling or tingling
- heart burn
- haemorrhoids
- blocked nose
- eczema
- night sweats
- acne (pimples)
- injection site reactions (including pain, swelling, redness or itching)
- shingles (herpes zoster)

Uncommon side effects (may affect up to 1 in 100 people)

- redness and tenderness of hair follicle
- throat and mouth yeast infection
- vaginal infection
- blurred vision (loss of sharpness of eyesight)

Very rare side effects (may affect up to 1 in 10,000 people)

- sudden, severe allergic reaction which can cause breathing difficulty, swelling, fast heartbeat, sweating, drop in blood pressure, light-headedness, loss of consciousness and collapse (anaphylactic reaction and anaphylactic shock)
- inflammation of the liver (hepatitis). Signs and symptoms of hepatitis may include abnormal liver function tests, eye or skin yellowing (jaundice), pain on the right side of your stomach area, bruising

Not known (frequency cannot be estimated from the available data)

- lung disease causing shortness of breath (interstitial lung disease)

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 Entyvio

- 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 carton after “EXP”. The expiry date refers to the last day of that month.
- Entyvio is for single use only.
- Store in a refrigerator (2 °C-8 °C). Keep the pre-filled pen(s) in the original carton in order to protect from light. If needed one pre-filled pen can be left out of the refrigerator protected from light at room temperature (up to 25 °C) for up to 7 days. Do not use if left out of the refrigerator for more than 7 days.
- Do not freeze. Do not leave in direct sunlight.
- Do not use this medicine if you notice any particles in the liquid or discolouration (should be colourless to yellow) prior to administration.
- Do not throw away any medicines via wastewater or household waste. Ask your 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 Entyvio contains**

- The **active substance** is vedolizumab. Each pre-filled pen contains 108 mg of vedolizumab.
- The **other ingredients** are citric acid monohydrate, sodium citrate dihydrate, L-histidine, L-histidine monohydrochloride, L-arginine hydrochloride, polysorbate 80 and water for injections.

What Entyvio looks like and contents of the pack

- Entyvio is a colourless to yellow solution for injection provided in a glass pre-filled pen equipped with an automated needle shield to extend and lock over the needle once the device is removed from the injection site.
- Entyvio is available in cartons containing 1 or 2 pre-filled pens and in multipacks containing 6 (6x1) pre-filled pens. Not all pack sizes may be marketed.

Marketing Authorisation Holder

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Other sources of information

This leaflet is available in formats suitable for the blind or partially sighted patient and can be requested from the Marketing Authorisation Holder.

The following information is intended for healthcare professionals only:

Traceability

In order to improve the traceability of biological medicinal products, the name and the batch number of the administered product should be clearly recorded

Instructions for use:

Read and follow these instructions before you inject. Your doctor, nurse or pharmacist should show you how to use the Entyvio pre-filled pen before you use it for the first time.

Your Entyvio single-dose pre-filled pen

Before Use

Purple Cap Viewing window

After Use

Yellow needle shield Viewing window
(Completed Injection)

1) Place what you need for the injection on a clean flat surface

- Take the pre-filled pen carton out of the refrigerator.
- If you are opening the carton for the first time, check to make sure the carton is properly sealed. **Do not** use the pre-filled pen(s) if any of the seals on the carton are broken or missing.
- Check the expiry date (EXP) on the carton. **Do not** use if the expiry date on the carton has passed.
- Remove one pre-filled pen from the carton. Keep any remaining pre-filled pens in the carton in the refrigerator.
- Wait **30 minutes** to let the pre-filled pen come to room temperature.
- **Do not** warm the pre-filled pen in any other way.
- **Do not** let it sit in direct sunlight.
- **Do not** take the pre-filled pen out of its tray until you are ready to inject.
- You will also need:
 - Alcohol pad
 - Cotton ball or gauze

Wait 30 minutes

- Sharps disposal container

2) Open and check the pre-filled pen

- Wash your hands.
- Peel back the paper on the tray and lift the pre-filled pen out.
- Inspect the pre-filled pen for damage.
 - **Do not** use the pre-filled pen if any part of it is damaged.
- Check the expiry date on the pre-filled pen.
 - **Do not** use if the expiry date on the pre-filled pen has passed.
- Check the medicine. It should be colourless to yellow.
 - **Do not** use the pre-filled pen if the medicine is cloudy or has particles floating in it.
- You may see air bubbles in the pre-filled pen. This is normal.
 - **Do not** shake

3) Prepare the injection site

- **Choose an injection site** on your bare skin from 1 of the following:
 - Front of the thighs, or
 - Stomach area (abdomen) except for the area 5 cm around the belly button (navel), or
 - Back of the upper arm (only if a caregiver gives the injection).
- Use a new injection site or a different area within the same injection site for each injection.
 - **Do not** inject into moles, scars, bruises, or skin that is tender, hard, red, or damaged.
- Wipe the chosen site with an alcohol pad. Let your skin dry.
 - **Do not** touch this area again before you inject.
- Pull the purple cap straight off and throw it away.
 - **Do not** put or press thumb, fingers or hand over the yellow needle shield.
 - **Do not** re-cap the pre-filled pen.
 - **Do not** use a dropped pre-filled pen.

4) Inject Entyvio

- Hold the pre-filled pen so you can see the viewing window.
- Place the pre-filled pen at **90 degrees** to the injection site.
 - Be sure the **yellow end is toward the injection site**.
 - **Do not** push down until you are ready to inject.
- **Push down on the pre-filled pen as far as it will go** to begin the injection.
- **Hold and count to 10** while pushing down with constant pressure. This will allow all of the medicine to be injected.
 - You may hear 2 clicks, one at the start and one near the end of the injection.
- **Confirm that the viewing window is filled with purple** before you stop pushing.
 - You will see a small amount of grey in the window. This is normal.
- Lift the pre-filled pen from the injection site.
 - The yellow needle shield will drop down and lock over the needle.
 - If the viewing window did not fill completely, call your doctor, nurse or pharmacist. You may not have received your full dose of medicine.
- You may see a small amount of blood at the injection site. If you do, press on your skin with a cotton ball or gauze.

PUSH

**HOLD
(Count to 10)**

CONFIRM

5) Throw away used material

- Put the used pre-filled pen in a puncture-resistant container, like a sharps container, immediately after use.
 - Dispose of your sharps container according to your local regulations.
- The rest of the material can be thrown away in your household rubbish.