Package leaflet: Information for the patient

Entyvio 300 mg powder for concentrate for solution for infusion
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 or nurse.
- If you get any side effects, talk to your doctor 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 are given Entyvio
3. How Entyvio will be given
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, Crohn's disease and pouchitis. 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
- moderately to severely active chronic pouchitis

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.

Pouchitis
Pouchitis is a disease that causes inflammation of the lining of the pouch, which was created during surgery to treat ulcerative colitis. If you have pouchitis, you may first be given antibiotics. If you do not respond well enough to the antibiotics, your doctor may give you Entyvio to reduce the signs and symptoms of your disease.

2. What you need to know before you are given 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 or nurse before being given Entyvio.

Tell your doctor or nurse immediately when you first receive 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 or other reaction to the infusion** such as wheezing, difficulty breathing, hives, itching, swelling or dizziness. These could occur during or after the infusion. For more detailed information, see infusion and 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 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 contains polysorbate 80
This medicine contains 3.31 mg of polysorbate 80 in each Entyvio 300 mg vial. Polysorbates may cause allergic reactions. Tell your doctor if you have any known allergies.

3. How Entyvio will be given

How much Entyvio you will receive
Treatment with Entyvio is the same for ulcerative colitis, Crohn's disease and pouchitis.

The recommended dose is 300 mg of Entyvio given as follows (see table below):

Treatment (infusion) number	Timing of treatment (infusion)
Treatment 1	0 weeks
Treatment 2	2 weeks after Treatment 1
Treatment 3	6 weeks after Treatment 1
Further treatments	Every 8 weeks

Your doctor may decide to alter this treatment schedule depending on how well Entyvio works for you.

- The infusion will be given to you, by your doctor or nurse, through a drip in 1 of the veins in your arm (intravenous infusion) over about 30 minutes.
- For your first 2 infusions, your doctor or nurse will monitor you closely during the infusion and for approximately 2 hours after you have completed the infusion. For all subsequent infusions (after the first 2), you will be monitored during the infusion and for approximately 1 hour after you have completed the infusion.

If you forget or miss your Entyvio infusion
If you forget or miss an appointment to receive the infusion, make another appointment as soon as possible.

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 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, pain at the infusion site, redness of skin
- 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)
- rectal bleeding
- chest discomfort

- 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 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, and on the label, after "EXP". The expiry date refers to the last day of that month.

Entyvio is given by a doctor or nurse and patients should not need to store or handle Entyvio.

Entyvio is for single use only.

Unopened vial: Store in a refrigerator (2 °C-8 °C). Keep the vial in the original carton in order to protect from light.

Reconstituted and diluted solutions: Use immediately. If this is not possible, reconstituted solution in the vial can be stored for up to 8 hours at 2 °C-8 °C. Diluted solution in sodium chloride 9 mg/mL (0.9%) solution for injection can be stored up to 12 hours at a room temperature of not above 25 °C, or up to 24 hours in a refrigerator (2 °C-8 °C), or for up to 12 hours at room temperature and in a refrigerator (2 °C-8 °C), up to a combined total of 24 hours. A 24 hour period may include up to 8 hours at 2 °C-8 °C for reconstituted solution in the vial and up to 12 hours at 20 °C-25 °C for diluted solution in the infusion bag but the infusion bag must be stored in the refrigerator (2 °C-8 °C) for the rest of the 24 hour period Any time that the reconstituted solution was held in the vial should be subtracted from the time the solution may be held in the infusion bag.

Do not freeze.

Do not use this medicine if you notice any particles in the liquid or discolouration (solution should be clear or opalescent, colourless to light 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 vial contains 300 mg of vedolizumab.
- The **other ingredients** are L-histidine, L-histidine monohydrochloride, L-arginine hydrochloride, sucrose, and polysorbate 80 (E 433). See section 2 “Entyvio contains polysorbate 80”.

What Entyvio looks like and contents of the pack

- Entyvio is a white to off-white powder for concentrate for solution for infusion provided in a glass vial with a rubber stopper and a plastic cap.
- Each pack of Entyvio consists of one vial.

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 reconstitution and infusion

1. Use aseptic technique when preparing Entyvio solution for intravenous infusion.

2. Remove flip-off cap from the vial and wipe with alcohol swab. Reconstitute vedolizumab with 4.8 mL of sterile water for injections at room temperature (20 °C-25 °C), using a syringe with a 21-25 gauge needle.

3. Insert needle into the vial through the centre of the stopper and direct the stream of liquid to the wall of the vial to avoid excessive foaming.

4. Gently swirl the vial for at least 15 seconds. Do not vigorously shake or invert.

5. Let the vial sit for up to 20 minutes at room temperature (20 °C-25 °C), to allow for reconstitution and for any foam to settle; the vial can be swirled and inspected for dissolution during this time. If not fully dissolved after 20 minutes, allow another 10 minutes for dissolution.

6. Inspect the reconstituted solution visually for particulate matter and discolouration prior to dilution. Solution should be clear or opalescent, colourless to light yellow and free of visible particulates. Reconstituted solution with uncharacteristic colour or containing particulates must not be administered.

7. Once dissolved, gently invert vial 3 times.

8. Immediately withdraw 5 mL (300 mg) of reconstituted Entyvio using a syringe with a 21-25 gauge needle.

9. Add the 5 mL (300 mg) of reconstituted Entyvio to 250 mL of sterile sodium chloride 9 mg/mL (0.9%) solution for injection, and gently mix the infusion bag (5 mL of sodium chloride 9 mg/mL (0.9%) solution for injection does not have to be withdrawn from the infusion bag prior to adding Entyvio). Do not add other medicinal products to the prepared infusion solution or intravenous infusion set. Administer the infusion solution over 30 minutes.

Once reconstituted, the infusion solution should be used as soon as possible.

	Storage Condition	
	Refrigerator (2 °C-8 °C)	20 °C-25 °C
Reconstituted solution in the vial	8 hours	Do not hold[1]
Diluted solution in sodium chloride 9 mg/mL (0.9%) solution for injection	24 hours[2, 3]	12 hours[2]

[1] Up to 30 minutes are allowed for reconstitution
[2] This time assumes the reconstituted solution is immediately diluted in the sodium chloride 9 mg/mL (0.9%) solution for injection and held in the infusion bag only. Any time that the reconstituted solution was held in the vial should be subtracted from the time the solution may be held in the infusion bag.
[3] This period may include up to 12 hours at 20 °C-25 °C.

Do not freeze. Do not store any unused portion of the reconstituted solution or infusion solution for reuse.
Each vial is for single use only.

Any unused medicinal product or waste material should be disposed of in accordance with local requirements.