

## Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

### 1. Why am I using Entyvio?

Entyvio contains the active ingredient vedolizumab. Entyvio is used to treat the signs and symptoms of moderate to severe ulcerative colitis or moderate to severe Crohn's disease in adults who have not responded well enough or are intolerant to other treatments. Entyvio can also be used to treat the signs and symptoms of moderate to severe pouchitis in adult patients who have not responded well enough to antibiotics.

For more information, see Section [1. Why am I using Entyvio?](#) in the full CMI.

### 2. What should I know before I use Entyvio?

Do not use if you have ever had an allergic reaction to vedolizumab or any of the ingredients listed at the end of the CMI.

**Talk to your doctor if you have any other medical conditions, take any other medicines, are pregnant or plan to become pregnant or are breastfeeding or plan to breastfeed.**

For more information, see Section [2. What should I know before I use Entyvio?](#) in the full CMI.

### 3. What if I am taking other medicines?

Some medicines may interfere with Entyvio and affect how it works.

A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

### 4. How do I use Entyvio?

Entyvio powder for injection will be given to you by your doctor or nurse, through a drip in one of the veins in your arm (intravenous infusion) over about 30 minutes.

More instructions can be found in Section [4. How do I use Entyvio?](#) in the full CMI.

### 5. What should I know while using Entyvio?

|                                    |   |
|------------------------------------|---|
| <b>Things you should do</b>        | <ul style="list-style-type: none"><li>• Read this leaflet carefully before you start using this medicine. It contains important information for you.</li><li>• Keep this leaflet. You may need to read it again.</li><li>• If you have any questions, ask your doctor, pharmacist or nurse.</li></ul> |
| <b>Things you should not do</b>    | <ul style="list-style-type: none"><li>• Do not stop using Entyvio without checking with your doctor.</li><li>• Do not give this medicine to anyone else, even if they have the same condition as you.</li></ul>   |
| <b>Driving or using machines</b>   | <ul style="list-style-type: none"><li>• Be careful driving or operating machinery until you know how Entyvio affects you.</li><li>• If you feel dizzy, do not drive or use tools or machines.</li></ul>   |
| <b>Looking after your medicine</b> | <ul style="list-style-type: none"><li>• Store in a refrigerator at 2°C to 8°C. Do not freeze.</li><li>• Keep the vial in the original carton to protect from light.</li></ul>   |

For more information, see Section [5. What should I know while using Entyvio?](#) in the full CMI.

### 6. Are there any side effects?

Very common: common cold, joint pain, headache. Common: fever, flu (influenza), nose or throat infection, bronchitis, chest infection, chest discomfort, cough, throat pain, nausea, itching, rash and redness, pain in the extremities, back pain, tiredness, rectal bleeding. Serious side effects: allergic reactions, infections, liver injury.

For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

# Entyvio® IV

Active ingredient(s): vedolizumab

## Consumer Medicine Information (CMI)

This leaflet provides important information about using Entyvio. It does not take the place of talking to your doctor or pharmacist.

**You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using Entyvio.**

The information in this leaflet was last updated on the date listed on the final page. More recent information on the medicine may be available. You should ensure that you speak to your pharmacist or doctor to obtain the most up to date information on this medicine. You can also download the most up to date leaflet from [www.takeda.com/en-au](http://www.takeda.com/en-au). Those updates may contain important information about the medicine and its use of which you should be aware.

**Where to find information in this leaflet:**

- [1. Why am I using Entyvio?](#)
- [2. What should I know before I use Entyvio?](#)
- [3. What if I am taking other medicines?](#)
- [4. How do I use Entyvio?](#)
- [5. What should I know while using Entyvio?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

## 1. Why am I using Entyvio?

**Entyvio contains the active ingredient vedolizumab.**

Vedolizumab is a monoclonal antibody. Monoclonal antibodies are proteins that recognise and bind to certain special proteins in the body.

Entyvio specifically binds to a protein called integrin  $\alpha 4\beta 7$  present on certain white blood cells. Integrin  $\alpha 4\beta 7$  can act to increase inflammation seen in ulcerative colitis, Crohn's disease and pouchitis. Entyvio works by blocking  $\alpha 4\beta 7$  integrins and so reduces inflammation.

### Ulcerative colitis

Ulcerative colitis is an inflammatory disease of the large bowel. Entyvio is used to treat the signs and symptoms of moderate to severe ulcerative colitis in adults who have not responded well enough or are intolerant to other treatments.

### Crohn's disease

Crohn's disease is an inflammatory disease of the bowel. It may also affect any part of the gut. Entyvio is used to treat the signs and symptoms of moderate to severe Crohn's disease in adults who have not responded well enough or are intolerant to other treatments.

### 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 should I know before I use Entyvio?

### Warnings

**Do not use Entyvio if:**

- You are allergic to vedolizumab, or any of the ingredients listed at the end of this leaflet.
- Symptoms of an allergic reaction may include wheezing or difficulty breathing, hives, itching of the skin, swelling or dizziness.
- You have an active severe infection, such as for example tuberculosis, blood poisoning, serious abscesses.
- After the expiry date printed on the pack or if the packaging is damaged or shows signs of tampering. If it has expired or is damaged return it to your pharmacist for disposal.

**Check with your doctor if you:**

- Have an infection, or think you have an infection.
- Are going to receive any vaccination or have recently had a vaccination. Entyvio may affect the way you respond to a vaccination.
- Have any allergies to any other medicines, foods, preservatives or dyes.
- Take any medicines for any other condition.

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section [6. Are there any side effects?](#)

### Pregnancy and breastfeeding

**Tell your doctor if you are pregnant or intend to become pregnant.**

The effects of Entyvio in pregnant women are not known. Therefore, this medicine is not recommended for use during pregnancy unless you and your doctor decide that the benefit to you clearly outweighs the potential risk to your baby. Your doctor can discuss the risks and benefits involved.

If you are a woman of childbearing potential, you should use adequate contraception to avoid falling pregnant and continue to use it for at least 4.5 months after the last treatment with Entyvio.

**Tell your doctor if you are breastfeeding or intend to breastfeed.**

Entyvio passes into breast milk and it is not known what effect this may have on your baby.

Women who are breastfeeding or intend to breastfeed should talk to their doctor about whether or not to use Entyvio.

### Use in Children

There is not enough information to recommend the use of this medicine for children under the age of 18 years.

## 3. What if I am taking other medicines?

Tell your doctor or pharmacist if you are taking any other medicines, including any medicines, vitamins or supplements that you buy without a prescription from your pharmacy, supermarket or health food shop.

Entyvio should not be given with other biologic medicines that suppress your immune system as this combination has not been studied in clinical trials.

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 use Entyvio.

**Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect Entyvio.**

## 4. How do I use Entyvio?

### How much to use

- Treatment with Entyvio is the same for ulcerative colitis, Crohn's disease and pouchitis.
- The recommended dose of Entyvio is 300 mg per infusion. Following the initial dose, you will get additional infusions at 2 and 6 weeks and be assessed by your treating doctor 6 to 8 weeks after you've completed the initial treatment doses to see how you have responded.
- For patients with Crohn's Disease who have not shown response, your doctor may recommend an additional dose of Entyvio at week 10.
- If there has been an adequate response to the first 3 doses you may continue treatment with further doses every 8 weeks.
- For patients with ulcerative colitis or Crohn's disease, your doctor may decide to alter this treatment schedule to every 4 weeks depending on how well Entyvio works for you.

### How Entyvio is given

- Entyvio will be given to you by your doctor or nurse, through a drip in one of the veins in your arm (intravenous infusion) over about 30 minutes.
- Your healthcare provider will monitor you during and after the Entyvio infusion for side effects to see if you have a reaction to the treatment.

### How long to take it

- Continue receiving your medicine for as long as your doctor tells you.
- You should not stop using Entyvio without talking with your doctor first.

### If you forget to use Entyvio

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

**If you are not sure what to do, ask your doctor.**

### If you are given too much Entyvio

As Entyvio is given to you by infusion under the supervision of a doctor or nurse, it is unlikely that you will receive too much.

**However, if you experience any side effects after being given Entyvio, tell your doctor or nurse immediately.**

## 5. What should I know while using Entyvio?

### Things you should do

When you first receive this medicine and during the course of the treatment, also between doses, tell your doctor or pharmacist immediately if you:

- Have an **infection**, or think you have an infection, such as if you develop chills, shivering, persistent cough or a high fever. Some infections may become serious and possibly even life-threatening if left untreated.
- Experience signs of an **allergic reaction** or other reaction to the infusion such as wheezing, difficulty breathing, hives, itching, swelling or dizziness.
- Are going to receive any **vaccination** or have recently had a vaccination. Entyvio may affect the way you respond to a vaccination.
- If you are about to be started on any new medicine, remind your doctor that you are using Entyvio.
- If you become pregnant while you are taking this medicine, tell your doctor immediately.

### Call your doctor straight away 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, or memory loss or confusion. These may all be symptoms of a **serious and potentially fatal brain condition** known as progressive multifocal leukoencephalopathy (**PML**).

Remind any doctor, dentist or pharmacist you visit that you are using Entyvio.

### Things you should not do

- Do not use this medicine to treat any other complaints unless your doctor tells you to.
- Do not give this medicine to anyone else, even if they have the same condition as you.
- Do not stop using Entyvio without checking with your doctor.

### Driving or using machines

**Be careful before you drive or use any machines or tools until you know how Entyvio affects you.**

This medicine may have a minor influence 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.**

### Looking after your medicine

- If you need to store Entyvio before taking it to hospital or clinic, the unopened vial should be stored in the refrigerator at 2°C to 8°C (Refrigerate. Do not freeze).
- Keep the vial in the original carton to protect from light.
- Do not use this medicine after the expiry date.

Follow the instructions in the carton on how to take care of your medicine properly.

Store it in a cool dry place away from moisture, heat or sunlight; for example, do not store it:

- in the bathroom or near a sink, or
- in the car or on windowsills.

**Keep it where young children cannot reach it.**

## 6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

Do not be alarmed by this list of possible side effects. You may not experience any of them.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

### Less serious side effects

| Less serious side effects   | What to do  |
|---|---|
| <ul style="list-style-type: none"> <li>• headache</li> <li>• fever</li> <li>• common cold</li> <li>• flu (influenza)</li> <li>• nose or throat infection</li> <li>• bronchitis</li> <li>• chest infection</li> <li>• chest discomfort</li> <li>• cough</li> <li>• throat pain</li> <li>• nausea</li> <li>• itching</li> <li>• rash and redness</li> <li>• pain in the extremities</li> <li>• back pain</li> <li>• joint pain</li> <li>• tiredness</li> <li>• rectal bleeding</li> </ul> | <p><b>Speak to your doctor if you have any of these less serious side effects and they worry you.</b></p> |

### Serious side effects

| Serious side effects  | What to do   |
|---|--|
| <p><b>Allergic reactions – symptoms may include wheezing or difficulty breathing, hives, itching of the skin, redness of skin, swelling, vomiting or dizziness</b></p> <p><b>Infection or liver injury – symptoms may include chills or shivering, high fever, rash, dark urine, yellowing of the eyes and skin (jaundice)</b></p> <p><b>Inflammation of the pancreas - symptoms may include severe upper stomach pain, often with nausea and vomiting or stomach pain that spreads to your back.</b></p> | <p><b>Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.</b></p> |

**Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.**

Other side effects not listed here may occur in some people.

### Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at [www.tga.gov.au/reporting-problems](http://www.tga.gov.au/reporting-problems). By reporting side effects, you can help provide more information on the safety of this medicine.

**Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.**

## 7. Product details

This medicine is only available with a doctor's prescription.

### What Entyvio contains

|   |   |
|---|---|
| <b>Active ingredient (main ingredient)</b>      | Each vial of Entyvio contains 300 mg of vedolizumab.<br>After reconstitution each mL of solution contains 60 mg of vedolizumab. |
| <b>Other ingredients (inactive ingredients)</b> | histidine<br>histidine hydrochloride monohydrate<br>arginine hydrochloride<br>sucrose<br>polysorbate 80                         |

**Do not take this medicine if you are allergic to any of these ingredients.**

### What Entyvio looks like

Entyvio is a white to off-white powder provided in a glass vial.

Each pack of Entyvio contains one vial (AUST R 210048).

## **Who distributes Entyvio**

Entyvio is supplied in Australia by:

Takeda Pharmaceuticals

Australia Pty Ltd

Level 39, 225 George Street

Sydney, NSW 2000

Australia

Tel: 1800 012 612

[www.takeda.com/en-au](http://www.takeda.com/en-au)

Entyvio is supplied in New Zealand by:

Takeda New Zealand Limited

Level 10, 21 Queen Street

Auckland 1010

New Zealand

Tel: 0508 169 077

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