

## Consumer Medicine Information

This leaflet provides important information about using Entyvio pre-filled pen for subcutaneous injection. 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 pre-filled pen.**

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

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## 1. Why am I using Entyvio?

**Entyvio pre-filled pen 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 and Crohn's disease. 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.

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## 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. If you are breastfeeding, your doctor may advise you to stop breastfeeding while you are using this medicine.

### Use in Children

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

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

Tell your doctor or pharmacist if you are taking or have recently taken 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.**