

 **Entyvio**[®]
vedolizumab



YOUR TREATMENT WITH ENTYVIO

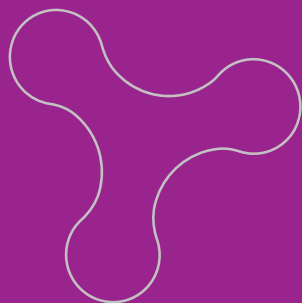
INFORMATION FOR PATIENTS WITH ULCERATIVE COLITIS
OR CROHN'S DISEASE BEING TREATED WITH ENTYVIO

YOUR TREATMENT WITH ENTYVIO

This brochure is for patients diagnosed with ulcerative colitis or Crohn's disease and are being treated with Entyvio.

Entyvio is currently available in two forms, Entyvio IV (intravenous) and Entyvio SC (subcutaneous) and may be given either by drip at your care clinic or as an injection, which can be taken at home in a pre-filled injection pen.

The brochure contains information about how Entyvio works, how it is used, and what you need to consider during your treatment.



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WHAT IS ENTYVIO?

Entyvio is a treatment used to reduce inflammation in the gastrointestinal tract in adults with moderate to severe ulcerative colitis or Crohn's disease.

It belongs to a group of treatments called biologicals and contains the active substance vedolizumab.

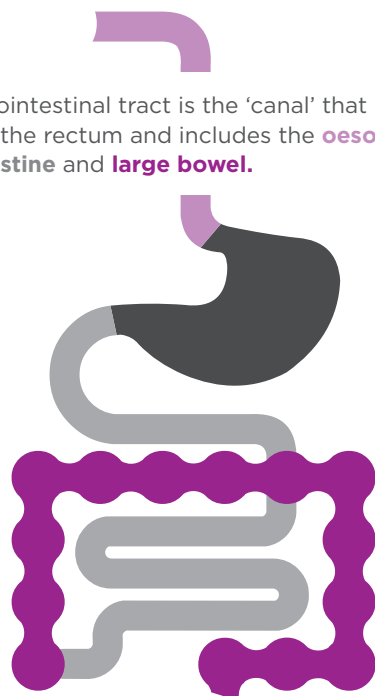
The treatment specifically targets the inflammation in the bowel, and it has no known impact on the rest of the body's immune system. By reducing the accumulation of white blood cells in the bowel in ulcerative colitis and Crohn's disease, Entyvio reduces the inflammation.

2 ABOUT ENTYVIO

WHAT IS ULCERATIVE COLITIS AND CROHN'S DISEASE?

Ulcerative colitis and Crohn's disease belong to the group inflammatory bowel diseases (IBD). The exact causes of ulcerative colitis or Crohn's disease are not yet known, but we do know that their symptoms are largely caused by **inflammation in the bowel**.

Ulcerative colitis primarily affects the large bowel, and Crohn's disease can affect all parts of the gastrointestinal tract (from the mouth to the rectum).



The gastrointestinal tract is the 'canal' that leads from the mouth to the rectum and includes the **oesophagus, stomach, small intestine** and **large bowel**.

WHY AM I BEING TREATED WITH ENTYVIO?

People who are given Entyvio have usually already tried other treatments but still show signs and symptoms of active disease.

You have probably had Entyvio prescribed by your doctor because you **have not responded well enough** to previous treatment, or your previous treatment has **stopped working** or has been causing side effects.



If you have any questions about your disease or your treatment, speak to your healthcare team.

HOW DOES ENTYVIO WORK?

Inflammation in the bowel

In an ulcerative colitis or Crohn's disease flare-up, white blood cells accumulate in the intestinal wall, and their inflammatory overactivity can cause damage, thus manifesting symptoms. One type of white blood cells, T lymphocytes **(a)**, play a central role in initiating and maintaining the inflammation.

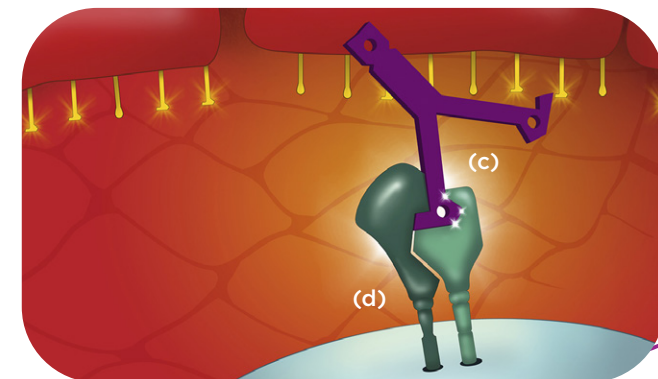
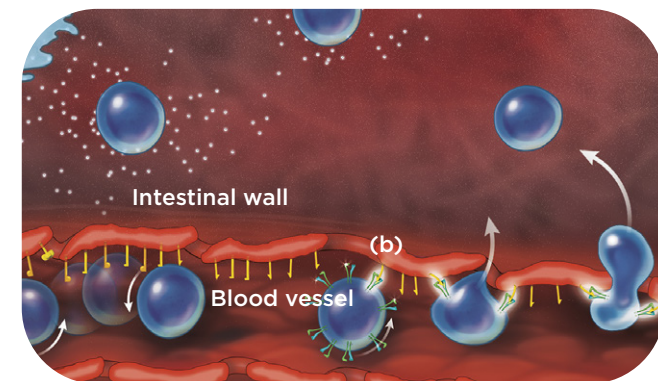
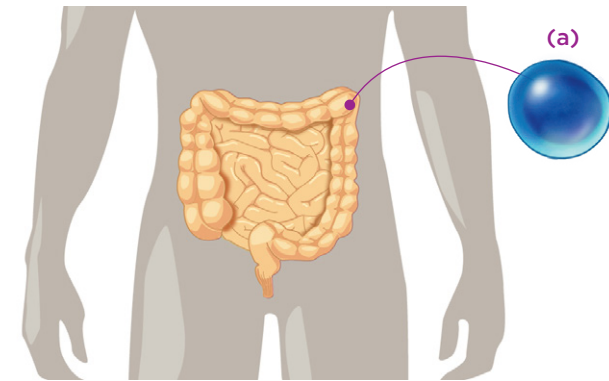
White blood cells accumulate in the bowel

T lymphocytes have a special protein on their cell surface which guides them to the right place in the body. When intestinal T lymphocytes roll along the walls of the veins, they don't stop until they encounter the right protein, the one that can only be found on the inside of blood vessels in the gastrointestinal tract. There, the cell binds on and finds its way into the intestinal wall **(b)**.

Entyvio inhibits white blood cells

Entyvio contains the active substance vedolizumab. Vedolizumab belongs to a group of biological treatments called monoclonal antibodies (MAbs). The antibody **(c)** binds the protein **(d)** on the surface of intestinal T lymphocytes. Blocking the protein prevents the white blood cells from penetrating the intestinal wall.*

This reduces the inflammation and gives the bowel an opportunity to heal.

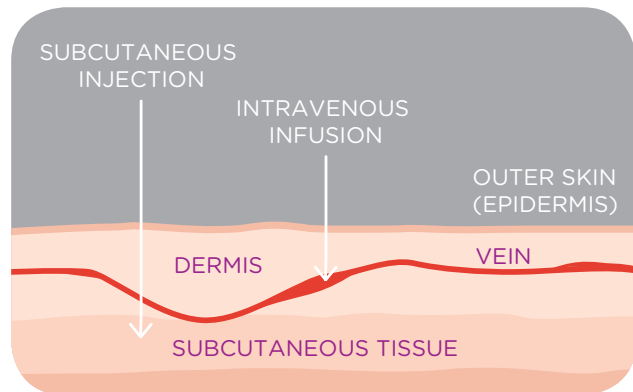


* Intestinal T lymphocytes have the protein $\alpha 4\beta 7$ integrin on the cell surface. $\alpha 4\beta 7$ integrin binds to the MAdCAM-1 protein on the surface of blood vessel cells in the bowel tissue. Vedolizumab binds and blocks $\alpha 4\beta 7$ integrin.

WHAT'S THE DIFFERENCE BETWEEN ENTYVIO GIVEN BY DRIP AND ENTYVIO GIVEN AS AN INJECTION?

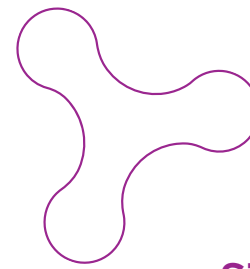
Entyvio comes in **two forms** – one is given by drip (intravenous infusion), and one as an injection under the skin (subcutaneous injection). Both forms contain **the same active substance** (vedolizumab) and can reduce the inflammation in the bowel in ulcerative colitis and Crohn's disease.

The main difference between the two forms of Entyvio is the way the drug gets into your body.



Intravenous infusion means the infusion is given **directly in the blood in the vein.**

Subcutaneous injection means the injection is given in **the tissue under the skin.**



STARTING WITH ENTYVIO

Your first doses of Entyvio will be given by drip (intravenous infusion).

Continued maintenance treatment with Entyvio will be given either as intravenous infusions or as subcutaneous injections.

- **Intravenous infusion**

Entyvio as an intravenous infusion is administered as a solution directly in the blood at the care clinic. A needle is inserted into a vein in your arm, a drip is connected to it and remains in place for about 30 minutes.

- **Subcutaneous injection**

Entyvio as an injection can be taken at home, following instructions and practice at the clinic. You can either administer the injection yourself, or ask a family member or close friend to help you.

Before you begin injection treatment with Entyvio, you must have at least two intravenous Entyvio infusions.



WHAT CAN I EXPECT FROM THE TREATMENT?

How and when you respond to a treatment varies between individuals. Therefore, have patience with your treatment as it may take some time before you notice any improvement.



Some respond quickly to the treatment and notice an improvement within six weeks.



The effects of Entyvio often come gradually and can take up to 14 weeks for patients with a more severe illness.

The response to a treatment varies between individuals. Some patients may get rid of their symptoms entirely and go into remission (a calm period with no symptoms), while other may notice a minor improvement and a few may see no improvement at all.

WHAT HAPPENS IF I DON'T GET BETTER FROM THE TREATMENT?

The effects of Entyvio can occur at different speeds, and for some patients it will take longer to respond to the treatment. An initial assessment of the treatment can be conducted after about **10-14 weeks**.

If your symptoms get worse during the treatment, speak to your healthcare team. Never stop or alter your treatment by yourself. **Follow the treatment instructions given to you by your doctor.**

WHAT HAPPENS IF I LOSE RESPONSE?

If you initially respond to the treatment but then start to lose response, you should **speak to your doctor**. Never stop or alter your treatment by yourself.



If you have any questions or comments about your medicine or treatment, don't hesitate to contact your healthcare team.

DOES ENTYVIO CAUSE SIDE EFFECTS?

All medicines can cause side effects, although not everyone gets them.

The most common side effects of Entyvio, which can occur in 1 in 10 patients, are:

- Common cold
- Joint pain
- Headache

There may also be a reaction to the infusion or at the injection site, such as pain, swelling, redness or itching. Such reactions usually wear off within 1-4 days.

Other side effects may also occur. These are listed in the patient information leaflet that comes with the treatment. Speak to your healthcare team if you have any questions or feel concerned about side effects.

What should I do if I experience side effects?

Tell your doctor or the healthcare team at the earliest opportunity if you experience side effects, even if they are not listed in the patient information leaflet.



Speak to your healthcare team if you have any questions or feel concerned about side effects.

IMPORTANT INFORMATION

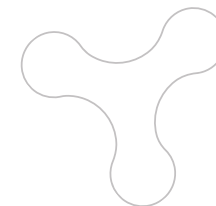
Before you begin treatment with Entyvio

Tell your doctor:

- If you think you have an active infection
- Whether or not you have been tested for tuberculosis
- If you are taking any other pharmaceuticals or treatments, as these may be affected by Entyvio
- If you are, or are planning to get, pregnant
- If you are, or are planning to, breastfeed
- If you are planning to have any vaccinations, as Entyvio may affect the efficacy of certain vaccines
- If you have cancer

Do not use Entyvio:

- If you have an active, severe infection – such as tuberculosis, blood poisoning, serious diarrhoea and vomiting (gastroenteritis) or infection of the nervous system.
- If you are allergic to vedolizumab or any of the other ingredients in this medicine (see patient information leaflet).



Tell your healthcare team immediately if you experience any of the following:

Signs of allergic reaction

- Breathing difficulties or wheezing
- Hives
- Itching, swelling or dizziness

Signs of severe infection

- Chills
- Shivering
- Persistent cough
- High fever

Signs that the nervous system is affected

The following may all be symptoms of a rare but serious infection known as progressive multifocal leukoencephalopathy (PML).

- Blurred, loss of or double vision
- Difficulty speaking
- Weakness in an arm or 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



3 TREATMENT WITH ENTYVIO

TREATMENT SCHEDULE



Intravenous drip

At least two intravenous infusions, administered at a care clinic

Your first doses of Entyvio will be given at the care clinic, as an intravenous drip, to see how you respond to the treatment.

The drip is administered via a vein in the arm and lasts for about 30 minutes. After the treatment, you will be asked to remain at the clinic for up to two hours for observation.

You may eat and drink as usual before the drip. Please bring a bottle of water and something to keep yourself occupied.

After at least two doses by intravenous drip, you can either continue with Entyvio as an intravenous drip (which is given at the care clinic every eight weeks or more frequently), or start injecting yourself at home.



Subcutaneous injection

Self-injections given at home

When Entyvio is taken at home, it is given with an automated pre-filled injection pen under the skin (subcutaneous injection) every other week.

The first subcutaneous injection is given at the time of the next scheduled intravenous infusion, and then every two weeks. Your doctor or nurse will explain everything you need to know to inject yourself safely and securely.

FOLLOWING YOUR TREATMENT SCHEDULE

To ensure the best possible effect from the treatment, it is important that you follow your treatment schedule.

If you miss a treatment appointment at your healthcare clinic, make sure to book a new appointment as soon as possible.

If you take Entyvio at home, it's important to take your injections as per your doctor's instructions. Never hesitate to ask a question if you feel in any way unsure.

To make it easier to remember your injections, it may be a good idea to:

- Always take your dose of treatment on the same day of the week, at the same time
- Set reminders in your phone/calendar
- Plan prescription renewals well in advance

If you miss a dose of Entyvio, take the next injection as soon as possible and then continue to inject every two weeks.

Do not stop the treatment without talking to the healthcare team first.



At www.entyviopatient.se you can find a step-by-step instruction video, which show you how to inject yourself with an Entyvio pre-filled injection pen.

USING ENTYVIO SELF-INJECT

Storage of the Entyvio pre-filled injection pen

- Store the Entyvio injection pen in the fridge (2–8°C). Store the pens in their outer box, as they are light sensitive.
- When necessary, e.g. if you are travelling, Entyvio can also be stored in the outer box at room temperature (up to 25°C) for up to seven days. Do not use the pre-filled injection pen if it has been stored outside the fridge for more than seven days.
- Do not freeze.
- Do not leave Entyvio in direct sunlight.

PREPARING ENTYVIO SELF-INJECT

Before you start injecting yourself with Entyvio at home, your doctor or nurse will explain everything you need to know and show you what to do.

The next few pages contain step-by-step instructions on injecting Entyvio with a pre-filled injection pen.

Always carefully read the patient information leaflet that comes with the treatment.

HOW DO I PREPARE FOR AN INJECTION?

It may feel unpleasant the first time you give yourself an injection. It often feels easier if you're properly prepared. With a little practice and patience, most people find it all right.

If you have had injections or infusions before, you know what a needle prick feels like – it's often the actual prick that many people find unpleasant. It may help to think about the fact that a lot of people inject their treatment themselves, whether they have UC, CD or some other illness.

It may be worth asking someone close to you for support in the beginning – not just with the practical stuff, but also emotional support.

TIPS BEFORE SELF-INJECTION

Prepare yourself mentally

- Relax – possibly try some deep-breathing exercises.
- Talk to your healthcare team, partner or someone else close to you, and let them support you.
- Think of everything that makes it worth taking the injection.

Before the injection

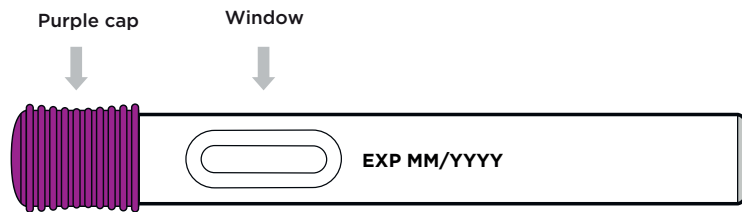
- Give yourself time to prepare, and read through the step-by-step instructions carefully.
- Think about what you did when you practised self-injecting with your nurse or doctor at the clinic.
- Practise slowly counting to 10, so that it takes at least 10 seconds.
- Use a new injection site every time.

Prepare the treatment

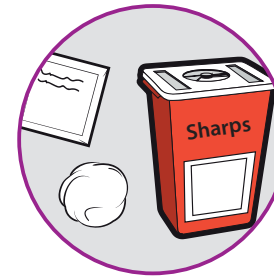
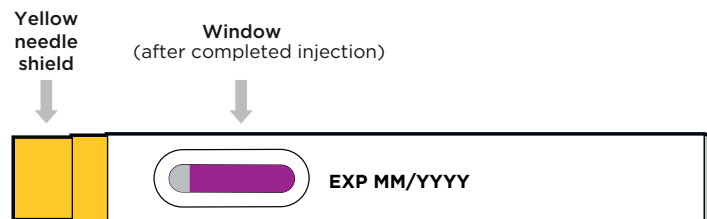
- Place the Entyvio pen at room temperature for about 30 minutes.

HOW TO USE THE ENTYVIO INJECTION PEN

Before the injection:

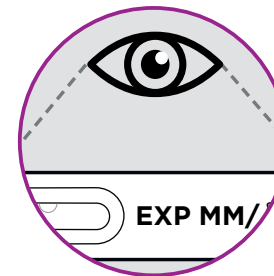


After the injection:



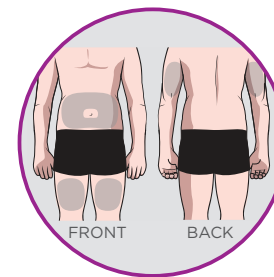
1) Preparation

- Find a quiet place where you won't be disturbed.
- **Gather everything you need for the injection and place it on a clean, flat surface.**
- **Take the box containing the injection pen out of the fridge and let it come up to room temperature (about 30 minutes).**
- Take out everything else you need:
 - an alcohol pad
 - a cotton wool ball or gauze
 - a sharps disposal container



2) Check the injection pen

- Wash your hands.
- Check the injection pen for any broken or missing seals
- Check the expiry date.
- Check that the medicine looks clear and colourless to yellow.
- You may see air bubbles in the injection pen. This is completely normal. **Do not shake the injection pen.**

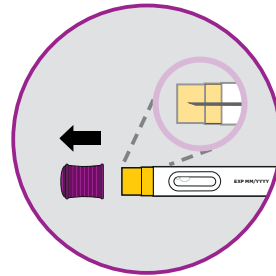


3) Choose an injection site

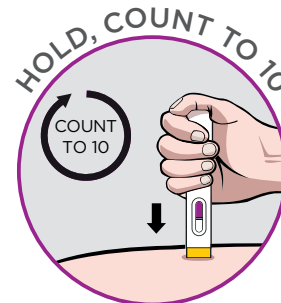
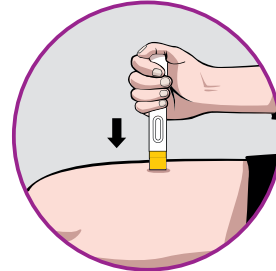
- Choose where the injection will be given - the front of the thigh, the stomach (but no closer than 5 cm to the belly button) or the back of your upper arm (only if someone else is giving you the injection).
- Make sure to **vary the injection site** each time you inject.
- **Do not inject** through birthmarks, scars, bruises or tender, hard, red or damaged areas of skin.
- Clean the chosen injection site with an alcohol pad. Let the skin dry. **Do not touch** this area again until the injection.

4) Inject Entyvio

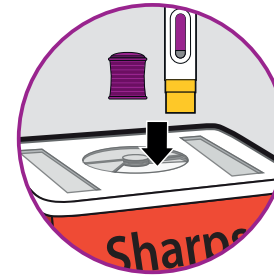
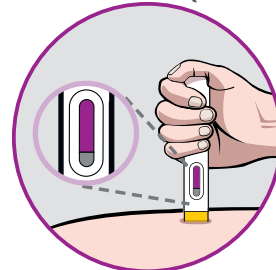
- Remove the purple cap by pulling directly away.
 - **Do not touch** the yellow needle shield.
 - **Do not use** the injection pen if you or anyone else has dropped it.
- Hold the pen so you can see the window.
- Hold the injection pen at **90 degrees** to the injection site. Make sure that **the yellow end is pointing towards the injection site. Do not press** until you are ready to inject.
- Make sure that the yellow end is held against the injection site.
- **Press the injection pen down onto the skin** to start the injection.
- **Hold it in place and count to 10** while pressing down steadily. This makes sure all the medicine gets injected. You may hear two clicks – one when the injection begins, and one towards the end of the injection.
- **Check that the window is purple** before you stop pressing the injection pen onto your skin.
- As well as purple, there will also be a little grey in the window. This is completely normal.
- Lift the injection pen away from your skin.
- The yellow needle shield covers the needle and protects it.
- If the viewing window did not fill up completely, contact your doctor, nurse or pharmacist. This may mean you did not receive the full dose.
- Press a cotton wool ball or gauze onto the injection site if any blood appears.



PRESS



CHECK



5) Tidy everything away

- Dispose of the used injection pen in a sharps container immediately after use.
- Sharps containers are available from Swedish pharmacies. If you do not have a sharps container, you can use a pot or package that:
 - is made of durable plastic or cardboard
 - has a tightly sealing, puncture-proof lid that prevents sharps from sticking out
 - stands steady and upright during use and does not leak
 - is marked with a warning that it contains hazardous waste
- You can put the other materials (purple cap, alcohol pad, cotton ball or gauze) in your household waste.
- Take your sharps container to a pharmacy when it is full.

UNDERSTAND YOUR ENTYVIO TREATMENT IN 5 MINUTES

Watch short videos on your phone, tablet or computer

The videos are intended as complements to this brochure, to give you greater understanding and peace of mind about your treatment with Entyvio.



Video on intravenous Entyvio

The video explains in simple terms what happens when you have intravenous Entyvio treatment at a care clinic.



Instruction video Entyvio injection pen

Step-by-step instructions on how to inject yourself with an Entyvio injection pen.

To watch the videos and for further information, go to www.entyviopatient.se – use the link or scan the QR code.



Now that you have read through this brochure, we hope you have had your questions answered, and that you feel comfortable and prepared for your treatment with Entyvio. If you have any questions or comments during your treatment period, please don't hesitate to contact your healthcare team.

Good luck with your ongoing treatment with Entyvio!

Entyvio[®] (vedolizumab), 300 mg powder for concentrate for solution for infusion, and 108 mg solution for injection in pre-filled pen.

What Entyvio is and what it is used for: Entyvio belongs to a group of biological medicines called monoclonal antibodies (MAb). 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 Chronic pouchitis (only Entyvio as an intravenous infusion)

Do not use Entyvio:

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

Warnings and precautions: Tell your healthcare provider immediately if you during or in between treatments experience signs of an allergic reaction, serious infection or signs that the nervous system is being affected, such as blurred vision, loss of vision 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. This medicine is not recommended during pregnancy. You and the doctor should decide whether the benefit to you outweighs the potential risks to you and the unborn baby. If you are a woman of childbearing potential, you should avoid becoming pregnant while using Entyvio. Use an appropriate contraceptive method during treatment and for at least 4.5 months after treatment has stopped. A decision must be made whether to stop breast-feeding or to stop using Entyvio taking into account the benefit of breast-feeding for your child and the benefit of therapy for you.

Carefully read the patient information leaflet before using Entyvio.

Abbreviated information based on the patient information leaflet dated 04/2023.

Contact: Takeda Pharma AB, infosweden@takeda.com, phone +46 8-731 28 00, www.takeda.se.



www.takeda.se

 **Entyvio**[®]
vedolizumab