

FREQUENTLY ASKED QUESTIONS

INFORMATION FOR PATIENTS AND CARERS

This document is only intended for use by a person after their healthcare professional has made the decision to treat them with Entyvio* subcutaneous (SC)

YOUR QUESTIONS AROUND ENTYVIO® (VEDOLIZUMAB)

This booklet contains some common questions that patients and carers may have around Entyvio® subcutaneous (SC) treatment, once it has been prescribed to them.

If you have any concerns or unanswered questions, please contact your healthcare professional.

You can also call Takeda Medical information on 01628 537900 or email DSO-UK@takeda.com with any questions.

If you experience any adverse events, you should report them immediately. In the United Kingdom, reporting forms and information can be found at www.mhra.gov.uk/yellowcard.

Adverse events should also be reported to Takeda Medical Information, you can call 01628 537900 or e-mail DSO-UK@takeda.com.



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RESPONSE TO ENTYVIO® TREATMENT

What is Entyvio®?

Entyvio® is a treatment for adults with moderately to severely active ulcerative colitis (UC) or Crohn's disease (CD). These conditions are collectively known as inflammatory bowel disease (IBD). The active ingredient in Entyvio® is vedolizumab. It's designed to target specific molecules in the body that are involved in the inflammation of the gut, which leads to the symptoms of IBD.¹

How quickly should I feel/see the effects of Entyvio®?

When Entyvio® intravenous (IV) infusion was tested by IBD specialists, around a third of patients responded to treatment by their second infusion – that's six weeks into their treatment.² Of those that respond to Entyvio®, some may see an improvement in their symptoms as early as two weeks into their treatment.^{1, 3} Others may improve gradually over time.^{1, 3}

Your doctor will check how your treatment is working around 10 weeks after your first IV infusion, to see how you are responding to Entyvio*. It may take up to 14 weeks to really feel a difference 1

I don't think that Entyvio® SC is working as well as the IV infusion I previously received, what should I do?

Entyvio® SC and IV were shown to work as well as each other in studies.¹ However, if you feel that you aren't responding as well as you were, tell your healthcare team as they might want to evaluate your treatment plan.

Are there any situations that I should not take Entyvio*, for example, if I have a fever or have to go to hospital for a reason other than my IBD?

If you have any concerns, please contact your healthcare professional for advice.

Should I discontinue therapy after a certain time if I don't see results? How will I know?

It is important to follow your treatment plan. If you have any questions regarding your treatment, please talk to your healthcare professional before stopping use of Entyvio®.

ENTYVIO® SC STORAGE

Where do I store the medication?

Entyvio® SC should be stored in a refrigerator between 2°C to 8°C (36°F to 46°F). **Do not** freeze your medication.

How do I store the medication?

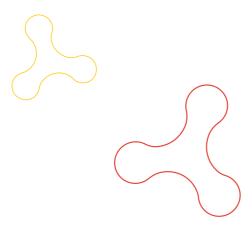
Entyvio® SC should be kept in a refrigerator in the original package and in the outer carton to protect it from sunlight. Entyvio® SC should never be frozen.

What happens if there's a power cut? How long can the product stay out of refrigeration?

Entyvio® SC can be stored at room temperature (up to 25°C or 77°F) for up to seven days, but it must be used within this time period. If Entyvio® SC has been at room temperature for more than seven days, **do not** use and please discard.

How long does my medicine need to be out of the refrigerator before I can use it?

Remove the medicine box from the refrigerator 30 minutes before use to allow it to reach room temperature (up to 25°C or 77°F) for injection.



INJECTING ENTYVIO® SC

General injection preparation

How does my treatment schedule work?

Before you can start injecting Entyvio® SC at home, you will need to have a few starter doses (sometimes called 'loading doses') given to you by a healthcare professional through an IV infusion. You need to have at least two infusions before you can start self-injecting. These will take place in a hospital and be supervised by a healthcare professional, probably an infusion purse.

If you have received at least two IV infusions (two weeks apart) and it is starting to work, you can begin using Entyvio® at home. The recommended dose is one injection every two weeks.¹

Why do I need to have the IV starter doses?

You will be given your starter doses through an IV infusion by someone on your healthcare team to make sure that your body responds well to Entyvio® before injecting yourself at home.

How do I begin using Entyvio® SC?

Your first doses of Entyvio® will be given as an IV infusion before you move onto Entyvio® SC. Someone on your healthcare team will be in charge of your infusion.

You will only be able to receive Entyvio® SC if you have already had Entyvio® IV starting doses previously. Either you or someone you choose will inject Entyvio® SC at home.

Depending on your hospital you may be eligible to receive a number of nurse visits at home to train you how to self-inject. Speak to your local healthcare professional to find out more.

How do I teach myself to self-inject effectively?

Read and follow the instructions for use that are inside your Entyvio® injection pen or syringe box before you inject. You may also want to consult your patient information booklet or seek advice from your healthcare professional.



Where can I self-inject with my Entyvio® SC?

You can inject Entyvio® SC either on the front of your thighs, stomach (not around the belly button) or back of the upper arm (if someone is doing the injection for you). Make sure you inject into a different part of the body from where you last injected.

Can I inject Entyvio® at the same site each time?

You should make sure to inject into a different place from the last time you used Entyvio® SC. You can inject Entyvio® SC either on the front of the thighs, stomach (not around the belly button) or back of the upper arm (if someone is doing the injection for you). It may be useful to keep a diary of where you inject to help you remember.

Are the instructions for someone else to administer the Entyvio* SC injection different than those for self-injection? If so, where can these instructions be found?

Yes, the only difference is that they can administer an Entyvio® SC injection in the back of your arm.

These instructions can be found in your patient booklet, carer booklet and the instructions for use in your medicine box.

Do I have to administer the injection at the same time every two weeks?

We would suggest that you try to take your medication on the same day, at the same time, every two weeks, in order to help you remember to take it. It might be helpful to record this in your calendar or mobile device so you don't forget.

Who can I call if I am having trouble administering the medication?

Please contact your healthcare professional or your homecare provider (the company that delivers your Entyvio* SC).

Can I switch from the Entyvio* syringe to the pen (and vice versa)?

Please speak to your healthcare professional to discuss changing how to administer Entyvio® SC.

What should I do if I miss a scheduled dose?

Please call your healthcare professional immediately.

Injection pen: before my injection

If the injection pen appears damaged, but still looks like it will work, should I still try to use it?

Do not attempt to use the injection pen and contact your homecare provider.*

How long does my medicine need to be out of the refrigerator before I can use it?

Remove the medicine box from the refrigerator 30 minutes before use to allow it to reach room temperature (up to 25°C or 77°F) for injection.

Injection pen: after my injection

My injection pen doesn't seem to be working properly

Please contact your homecare provider.*

I heard a clicking sound when administering my pen. Is that normal?

When you inject using the pen, it is important to count to 10 to ensure all the medicine gets into your body. You may hear two clicks, one at the start and one near the end of the injection.

How do I know if I administered the full amount of Entyvio*?

The viewing window will fill with purple. There may be a small amount of grey visible in the window but this is normal.

What happens if I don't administer the entire pen?

Please contact your healthcare team immediately.

^{*}Your homecare provider is the company that delivers your Entyvio* SC.

Prefilled syringe: before my injection

Are air bubbles in the prefilled syringe normal? Should I try to remove the air bubbles?

Consult the instructions for use. You may see air bubbles in the prefilled syringe and that is normal. Do not remove air bubbles or shake the prefilled syringe.

If the syringe appears damaged, but still looks like it will work, should I still try to use it?

Do not attempt to use the syringe and contact your homecare provider.*

How long does my medicine need to be out of the refrigerator before I can use it?

Remove the medicine box from the refrigerator 30 minutes before use to allow it to reach room temperature (up to 25° C or 77° F) for injection.

Prefilled syringe: after my injection

My prefilled syringe doesn't seem to be working properly

Please contact your homecare provider* immediately.

What happens if I don't administer the entire syringe?

Please contact your healthcare team immediately.

Some of the medication spilled out after I stopped pushing/pulled out the needle.

Please contact your homecare provider* immediately.

^{*}Your homecare provider is the company that delivers your Entyvio* SC.

USING THE PRACTICE INJECTION PEN/SYRINGE WITH YOUR HEALTHCARE PROFESSIONAL

How is the practice injection pen/syringe different from the real injection pen/syringe?

The practice injection pen/syringe is meant to look and operate like the real device. However, there are some important differences; the practice injection pen/syringe is resettable and reusable and does not contain a needle or medicine

Does the real pen reset like the practice pen?

No, the real pen does not reset. Do not attempt to reset or recap your real Entyvio® pen. Please dispose of it after use in a sharps bin.

Does the real syringe reset like the practice syringe?

No, the real syringe does not reset. Do not attempt to reset or recap your real Entyvio® syringe. Please dispose of it after use in a sharps bin.

How do I know I'm ready to self-inject?

Your healthcare professional, who will provide you with injection training, will let you know when they feel you (or the person you choose to do your injections) are ready to inject Entyvio* SC. If you need further guidance, you can talk to your healthcare professional.

I feel like I need additional instructions and/or help to use Entyvio® SC.

If you need additional information, please talk to your homecare provider.* Additional instructions can also be provided by your healthcare professional.

If someone else is going to administer the real injection for me, do they also need to practise with this device?

If Entyvio® SC will be administered by someone else, they can be trained by a healthcare professional with the Entyvio® practice syringe/pen in the same way that you can be.

^{*}Your homecare provider is the company that delivers your Entyvio* SC.

CONCERNS OVER REACTION TO DOSE/POTENTIAL ENTYVIO® SIDE EFFECTS

What are the ingredients in Entyvio®?

The ingredients in Entyvio® SC are as follows:

Vedolizumab, citric acid monohydrate, L-arginine hydrochloride, L-histidine, L-histidine monohydrochloride, polysorbate 80, sodium citrate dihydrate, and sterile water for injection.¹

Is Entyvio® SC latex free?

The product is manufactured without natural rubber latex, but as it is extremely difficult to ensure that nobody in the supply chain has used a latex glove in processing, we cannot claim that the product is 'latex free'.

What are side effects?

Side effects are unwanted effects caused by medical treatment. They're also called 'adverse events' or 'adverse reactions'. All medicines can cause side effects.⁴

What should I do if I think I'm experiencing side effects?

If you notice any changes in your health that you think might be related to your medicine, talk to your healthcare team. This includes any possible side effects not listed in the Patient Information Leaflet (PIL). You can also report side effects directly via Yellow Card Scheme. Visit the website: yellowcard.mhra.gov.uk or search for MHRA Yellow Card in the Google Play or Apple App Store for more information.

By reporting side effects, you can help provide more information on the safety of Entyvio*.





What are the most common side effects I should look for?

Your doctor might have told you that Entyvio® has a favourable safety profile. This means that when it's been studied in clinical trials, it had a low level of side effects.^{1,5}

The most common side effects (that happened in more than one in 10 people) were:

- Headache
- · Runny nose
- · Joint pain
- Tiredness

For a full list of side effects you can read the Entyvio® PIL which you can find in the packaging of your medicine.

There's some important safety information we have to tell you about. Progressive multifocal leukoencephalopathy (PML) is a rare, but serious and potentially fatal infection that can happen in people receiving certain treatments that target the same kind of molecules that Entyvio® works on.^{1,6}

You should look out for these symptoms:6

- 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

Tell your healthcare professional immediately if any of these symptoms start or get worse.

How do I prevent pain from the injections?

If you're worried about the injection hurting, you can numb the injection area with an ice cube.

What happens if Entyvio® is accidentally ingested by mouth?

Please contact your healthcare professional immediately.

DISPOSAL OF MY INJECTION PEN/SYRINGE

How do I dispose of the injection pen/syringe after use?

Put the injection pen/syringe into a sharps container straight away – don't put the pen/syringe in your normal rubbish. You should store your sharps bin in a place where it cannot be easily accessed, to avoid the risk of an accident

- You can put the rest of the items (the cap, the alcohol wipe, the cotton wool ball or gauze) in your normal rubbish or in the sharps bin
- When your sharps bin is almost full, you will need to get rid
 of it. Please contact your homecare provider* to arrange
 removing your bin

How do I get a sharps disposal container?

Please contact your homecare provider.*

Can I reuse my sharps disposal container?

No, you cannot reuse your sharps disposal container and do not attempt to empty the container when it is full. When your disposal container begins to look full, please let your homecare provider* know.

How should I dispose of my sharps if I don't have a sharps container?

If you don't have a sharps container please contact your homecare provider* immediately to arrange your delivery and use a container that:

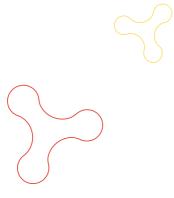
- Is made of heavy-duty plastic
- Can be closed with a tight-fitting, puncture-resistant lid without anything being able to come out
- · Is upright and stable during use
- · Is leak resistant
- Is properly labelled to warn of hazardous waste inside the container

^{*}Your homecare provider is the company that delivers your Entyvio* SC.

When your sharps bin is almost full, you will need to get rid of it. Please contact your homecare provider* to remove your full bin and provide you with a new one.

Can I recycle the plastic syringe/pen?

The plastic syringe/pen is for single use only. Please refer to your PIL for further information.



^{*}Your homecare provider is the company that delivers your Entyvio* SC.

ENTYVIO® SC SUPPLY AND DELIVERY

Do I have to be home to receive my shipment of Entyvio® SC?

A signature is required for delivery, which can be signed by either you or an authorised person on your behalf. The contents should be refrigerated immediately after delivery.

Do I have to be the one who signs for my shipment of Entyvio® SC?

A signature is required for delivery, which can be signed by either you or an authorised person on your behalf.

I left my shipment of Entyvio® SC out too long - what should I do?

Please refer to the PIL for storage information and contact your homecare provider* for further advice.

How do I get my shipment of Entyvio® SC delivered to a different address?

Please contact your homecare provider* to arrange your delivery.

I need an emergency delivery of Entyvio® SC - how do I get that?

Please contact your homecare provider.*

The shipping box that the Entyvio* SC was delivered in appears to be damaged. How will I know if I can still use it?

Please contact your homecare provider* for further information.

How do I request a same-day delivery of Entyvio® SC?

This service might not be included in your homecare provider* delivery package. Please contact your homecare provider* for further information.

My shipment of Entyvio[®] SC never arrived (or was lost) - what should I do to get my medication?

Please contact your homecare provider.*

^{*}Your homecare provider is the company that delivers your Entyvio* SC.

TRAVELLING WITH ENTYVIO® SC

What are the instructions for travelling with the medication? How long is it stable for?

While travelling, Entyvio® SC can be carried with an ice pack in a small cool bag that you can buy from a pharmacy. Carry your medicine in your hand luggage in case your checked-in luggage is lost.

If needed, for example when you are travelling, Entyvio® SC can be left in its box at room temperature (up to 25°C or 77°F) for up to seven days. Do not leave in direct sunlight.

Should I put my Entyvio® SC in the refrigerator if it has been at room temperature?

Temperature fluctuations should be avoided with Entyvio® SC – once it reaches room temperature (up to 25°C or 77°F) it should not be placed in the refrigerator.

How do I take Entyvio® SC through airport security? Do I need a bracelet or card indicating that I can have needles?

Before you go, it is a good idea to check your airline's hand luggage restrictions policy, particularly with carrying syringes and needles. Before you travel you can request a signed letter or travel certificate from your healthcare professional, confirming you can take Entyvio® SC with you.

Some people choose to wear 'Medic Alert' or Medical ID bracelets that identify their condition.

What if I have to take out my Entyvio* SC for inspection? Can I put it back into the cool bag?

You may be asked by airport security to open the cool bag to check your medicine – don't worry, opening the bag for a short period of time won't affect the temperature of the cool bag and the medicine should stay cool. You should try to return your medicine to the cool bag and close it as quickly as possible and then store as instructed above to ensure it stays cool.

What temperature is considered room temperature?

Room temperature is defined as 20-25°C (68-77°F).

Can I place Entyvio® SC in the refrigerator after travelling with it?

When you arrive at your destination, Entyvio* SC should be stored at 2°C to 8°C (36°F to 46°F) – remember that you must never freeze Entyvio* SC.

Temperature fluctuations should be avoided with Entyvio* SC - once it reaches room temperature (up to 25°C or 77°F) it should not be placed in the fridge.

Entyvio® SC can be left in its box at room temperature (up to 25°C or 77°F) for up to seven days. Do not leave in direct sunlight.

How long can Entyvio* SC be left out of the refrigerator for when travelling?

If needed, for example when you are travelling, Entyvio® SC can be left in its box at room temperature up to 25°C (77°F) for up to seven days.

Can I travel on a plane/train/bus/car with my sharps container?

Please contact your homecare provider* for advice and support.

How do I dispose of my sharps when overseas?

When overseas, try to plan before travelling where you can dispose of your sharps safely, such as a local health centre or pharmacy.

^{*}Your homecare provider is the company that delivers your Entyvio* SC.

NOTES

REFERENCES

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