

MY STELARA[®] TREATMENT GUIDE

janssen  Immunology

PHARMACEUTICAL COMPANIES OF *Johnson & Johnson*

This document has been reviewed and approved by
The Saudi Food and Drug Authority (SFDA).

Version 1, reviewed by SFDA in March 2022.

Introduction

Why you have been given this guide

You have been given this guide because you **have been prescribed Stelara®** (ustekinumab), a biologic therapy, **to treat your ulcerative colitis (UC) or Cohn's disease (CD)**.

The aim of this guide is to provide you with everything you need to **know about Stelara®** in order for you to **get the most out of your treatment**.

The information here will help you understand **how to take Stelara®, what to expect from it** and address **any questions, worries or doubts** you may have.

If you experience any side effects while on treatment with Stelara®, even if these are not listed in the package leaflet, talk to your treating physician or nurse.

You can report any side effects via:

Website: <https://ade.sfda.gov.sa>

Email: npc_drug@sfda.gov.sa

Call center number: 19999

You can report side effects to Johnson & Johnson:

Website: <https://jnprd.agcloud.bz/LSM35/home.html>

Mailbox: GCC-PV2@its.jnj.com

Hotline: +966540015811

If you are unfamiliar with some terms in this guide, please look at the **Glossary** section on the last page.

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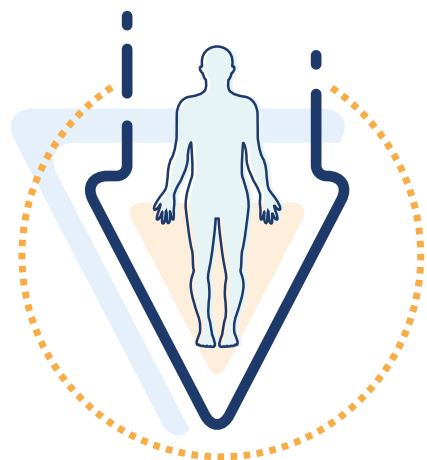
FAQs

About Stelara®

What is Stelara®?²

Stelara® is a **biologic therapy** (produced from living organisms)¹ used to treat adult patients with **Crohn's disease, ulcerative colitis, psoriasis** and **psoriatic arthritis**.

Stelara® belongs to a group of medicines called 'immunosuppressants', that act by **suppressing or dampening down the immune system**.



How Stelara® works³

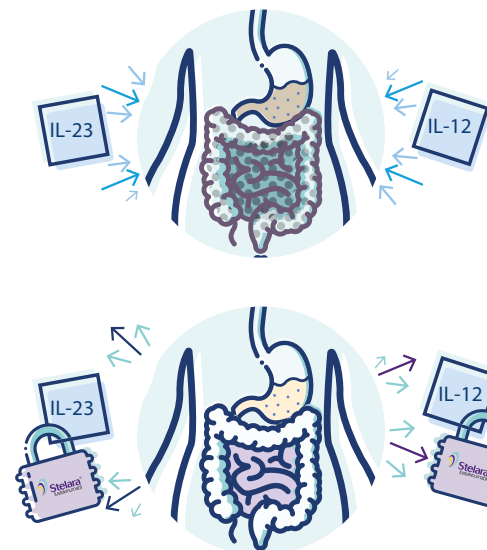
Stelara® contains the active substance 'ustekinumab'.

Ustekinumab is a monoclonal antibody, a type of protein that has been designed to recognise and attach to a specific target in the body.

Ustekinumab attaches to two proteins called interleukin-12 and interleukin-23.

Both are involved in inflammation and other processes that are important in psoriasis, psoriatic arthritis, Crohn's disease and ulcerative colitis.

By blocking the activity of interleukin-12 and interleukin-23, ustekinumab reduces the activity of the immune system and the symptoms of the disease.



When should you expect an improvement in your symptoms?²

In clinical studies, some patients already experienced an **improvement** in their **IBD symptoms** as early as **three weeks** after initiating treatment, although **most people** started **feeling better** within **8 weeks** and for some it took longer.

If you don't feel Stelara® is working for you, please make sure you discuss this with your treating physician or nurse.

Taking Stelara®

What to know before taking Stelara®²

DO NOT USE STELARA® IF YOU:

- Are allergic to ustekinumab or any of the other ingredients of this medicine (*L-histidine, L-histidine monohydrochloride monohydrate, polysorbate 80 and sucrose*)
- Have an active infection which your treating physician thinks is important



WHEN NOT TO USE STELARA®

You should **not use Stelara®**:

- **After the expiry date** stated on the packaging (both on the label and the carton after "EXP")
- **If the liquid is not clear** and colourless to light yellow
- **If the liquid is cloudy** or you can see foreign particles floating in it
- If you know it has, or think it may have been **exposed to extreme temperatures** (such as accidentally frozen or heated)
- If the product **has been strongly shaken**
- If the seal is **broken**

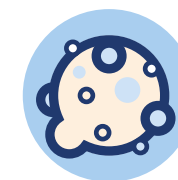


Before you use Stelara®, tell your treating physician or nurse if you:²



- Have ever had an **allergic reaction** to Stelara® (signs may have included difficulty in breathing or swallowing, dizziness, swelling of the face, skin rash and hives). *Ask your doctor if you're not sure*
- Are having any **other treatment** for ulcerative colitis or Crohn's disease
- Are having or have ever had **injections to treat allergies**

- Have ever had **any type of cancer** – this is because Stelara®'s suppression of the body's immune system may increase the risk of cancer



- Have or have had a recent **infection**

- Have ever had an **allergic reaction to latex** – the container of this medicinal product contains latex rubber, which may cause severe allergic reactions in people who are sensitive to latex



- Are **65 years of age or over** – this is because you may be more likely to get infections



- Have or have had **tuberculosis**, or have been in close contact with someone who has tuberculosis

- Are **pregnant** or are planning to become pregnant



- Are **breastfeeding** or plan to breastfeed



If you are not sure if any of the above applies to you, talk to your treating physician or nurse before using Stelara®.

How to take Stelara®²

Stelara® is intended for use **under the guidance and supervision** of a **healthcare provider** experienced in treating the conditions for which it is indicated. Always **use this medicine exactly as your doctor or nurse has told you**.

- You will receive your **first dose of Stelara®** in the form of an **intravenous infusion** (through a liquid drip in the vein of your arm) over at least one hour. Your doctor will work out the recommended dose you need based on your body weight
- After 8 weeks, you will then receive your **second dose of Stelara®**, this time in the form of an injection under your skin (**subcutaneous injection**). After this, you will probably receive Stelara® injections every 12 or 8 weeks
- If you and your doctor or nurse decide that you **can self-inject** your Stelara® treatment at home on your own, you will be trained on how to do this

Talk to your treating physician or nurse if you have any further questions about how to take Stelara®.



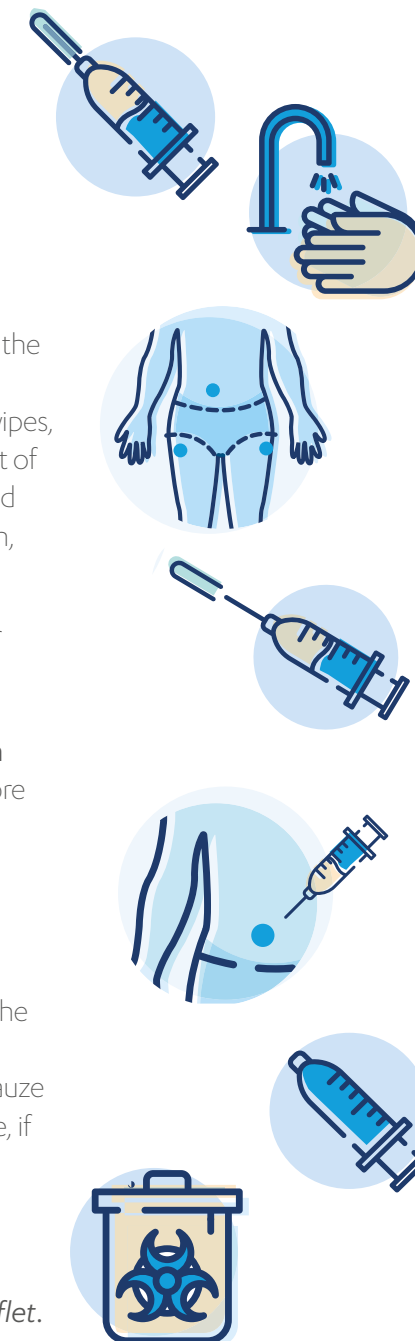
Your step-by-step Stelara® self-injection guide²

STELARA® CAN BE SELF-INJECTED IN SIX SIMPLE STEPS:

- 1** Take your carton of Stelara® out of the fridge and **check** both the **dose** and the **expiry date** printed on the box. Prepare the materials on a clean surface: your pre-filled syringe, antiseptic wipes, a cotton ball or gauze, and a sharps container. Take the pre-filled syringe out of the refrigerator and **let it stand for about half an hour**. This will let the liquid come to a comfortable temperature for injection (room temperature). Then, get everything together that you need and lay out on a **clean surface**.
- 2** **Choose and prepare the injection site** in your upper thigh or around your stomach area. Remember to stay at least 5 cm away from your belly button. **Wash your hands very well** with soap and warm water. **Wipe the injection site** on the skin with an **antiseptic wipe** – do not touch this area again before giving the injection.
- 3** **Prepare the dose** and **remove the needle cover**.
- 4** **Position the syringe** and **inject the dose**.
- 5** **Take the needle out of the skin** – it will automatically be drawn back into the syringe. Press an **antiseptic wipe over the injection site** for a few seconds after the injection – a little blood is normal. You can press a cotton ball or gauze pad to it if needed. Do not rub it. You can cover it with an adhesive bandage, if necessary.
- 6** **Dispose of the needle safely**. Never re-use needles and syringes.

For more information, please refer to the Stelara® patient information leaflet.

Version 1, reviewed by SFDA in March 2022.



Can Stelara® be used with other medications and vaccines?²

Inform your treating physician if you **are taking**, have **recently taken** or **might take** any other **medicines**.

You should also inform your treating physician or nurse if you have recently **had** or **are going to have a vaccination**. **Live vaccines**, those which contain a live, but weakened version of the virus, should **not be given** while using Stelara®. However, you **may receive “non-live or inactivated” vaccinations**, in which the disease-causing virus or bacterium is not active anymore. This includes vaccines such as those for the common flu and most of the recently developed COVID-19 vaccines.⁴⁻⁸

Before having or programming a vaccination, remember to always mention that you have IBD and the medication you are taking to treat it. If you have any queries or doubts about any vaccine or a vaccine not mentioned above, please ask your treating physician or nurse.



Most side effects are **mild to moderate** in nature. However, some people may experience **more serious** ones that **may require urgent attention and/or to stop treatment**. These include **allergic reaction including allergic lung reactions and lung inflammation, infections and shedding of skin**.²



COMMON SYMPTOMS of allergic reactions

- difficulty breathing or swallowing
- dizziness or light-headedness
- swelling of the face, lips, mouth or throat
- skin rash and hives²

COMMON SYMPTOMS of infections

- fever, flu-like symptoms, night sweats
- feeling tired or short of breath
- a cough which will not go away
- warm, red and painful skin, or a painful skin rash with blisters
- burning sensation when passing water
- diarrhoea

COMMON SYMPTOMS of shedding of skin

- increase in redness and shedding of skin over a larger area of the body

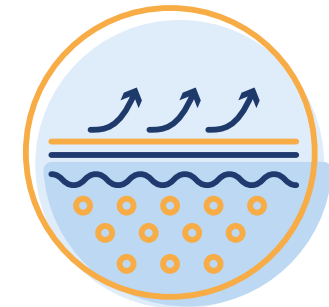
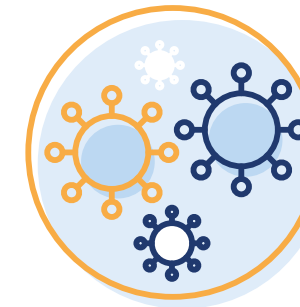
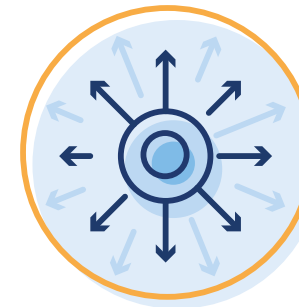
Side effects that you may experience with Stelara®²

Like all medicines, Stelara® **can cause side effects**, although **not everybody may have them**. The **most common side effects** (up to 1 in 10 people) are:²

DIARRHOEA
BACK, MUSCLE OR JOINT PAIN
NAUSEA
SORE THROAT

VOMITING
TIREDDNESS
SINUS INFECTION
(INFECTION OF NASAL CAVITIES)
DIZZINESS

REDNESS AND PAIN AT THE INJECTION SITE
HEADACHE
ITCHING



Inform your treating physician or nurse immediately if you experience any of the signs previously mentioned or any other side effect, even if it is not listed in this guide. Please refer to the Patient Information Leaflet for more details on side effects.²

How to fit Stelara® into your life

How to store Stelara®²

Store Stelara® in a **refrigerator** (2–8°C).

Do not freeze.

Keep the **pre-filled syringe in the outer carton** in order to protect from light.

Do not shake Stelara® pre-filled syringes, as prolonged, vigorous shaking may damage the medicine.

Stelara® should be kept **out of the sight and reach of children.**



Planning activities when taking Stelara®



You'll probably need to take Stelara® every 12 or 8 weeks.²

If you are flying, make sure there are **no restrictions on medications** at your destination and check if you need a note from your treating physician or nurse.

During your journey, it is advisable that you keep your Stelara® in its **original packaging** and all supplies needed for self-injection in your handbag or carry-on luggage, together with a letter from

your healthcare provider about your treatment.

If you are travelling **for more than 30 days**, you must make sure Stelara® will be kept refrigerated.² A **cool bag** in which an appropriate temperature can be maintained, may be a good option. If you are using Stelara® within 30 days, it can be left out of a refrigerator.² Remember: if your Stelara® filled syringe has been allowed to warm up to room temperature **DO NOT** put it back in the fridge and use it within 30 days.²

How to get the support you need



We hope this booklet helps you understand how to make the most of your newly prescribed Stelara® treatment. If you still have questions after reading it, please speak to your treating physician or treating nurse

FAQs

What is Stelara®?

Stelara® is a biologic therapy (produced from living organisms) used to treat a range of inflammatory conditions, including adult patients with Crohn's disease, ulcerative colitis, psoriatic arthritis and psoriasis. Stelara® belongs to a group of medicines called 'immunosuppressants', that act by suppressing or dampening down the immune system.

How do I take Stelara®?

Your first dose of Stelara® will be given as an infusion in the presence of a treating physician or nurse. After this, Stelara® is normally given as an injection under the skin. These can continue to take place with your treating physician or nurse or, if you and he/she agree, you may be trained so that you are able to inject yourself. Someone else, like a close friend or relative, may also be trained to help you.

What should I do if I've taken too much Stelara®?

If you've used or been given too much Stelara®, talk to your treating physician or nurse straight away. Always keep the outer carton of the medicine with you to show them, even if it is empty.

What should I do if I've missed a Stelara® dose?

If you forget a dose, please make sure you contact your treating physician or nurse. Do not take a double dose to make up for it.

What happens if I haven't injected a full Stelara® dose?

If you didn't inject the full dose you were prescribed, please make sure you contact your treating physician

or nurse. Do not take another dose to make up for the part you didn't inject.

What happens if I've injected Stelara® in the wrong site?

If you've injected Stelara® somewhere other than the recommended sites, please make sure you speak to your treating physician or nurse. The recommended injection sites are the upper thigh or around the belly (abdomen) at least 5 cm away from the belly button.

How will I feel with Stelara®?

Although everyone is different, many people with IBD who take Stelara® have found that their symptoms have improved, and some have achieved remission of symptoms altogether. However, some people may experience side effects, which can happen with any medicine. If you have side effects or feel that Stelara® isn't working for you, please make sure you speak to your treating physician or nurse.

When should I see an improvement with Stelara®?

You may already experience an improvement in your symptoms as early as three weeks after you start, although most people start feeling better within eight weeks and for some it takes longer.

What do I do if I don't think Stelara® is working for me?

Always use your medicine exactly as your treating physician or nurse has told you. If you don't feel Stelara® is working for you, please make sure you discuss this with your treating physician or nurse.

What do I do if I want to stop taking Stelara®?

Although it is not dangerous to stop using Stelara®, if you do, your symptoms may come back. Please make sure you speak to your treating physician or nurse if you are considering stopping your treatment.

How do I dispose of Stelara®?

Each dose of Stelara® is for single use only. Used syringes and needles should be placed in a puncture-resistant container. Never re-use needles, syringes and vials. Dispose of your container according to your local regulations. Empty vials, antiseptic wipes, and other supplies can be disposed of in your garbage.

How do I store Stelara®?

Store Stelara® in a refrigerator (2–8°C, do not freeze) out of the sight and reach of children. Do not shake the pre-filled syringes, as prolonged, strong shaking may damage the medicine.

Can I take other medications with Stelara®?

Tell your treating physician or nurse if you are taking, have recently taken, or might take any other medicines. If you have recently had or are going to have a vaccination, please let them know, as some types of vaccines (live vaccines) should not be given while using Stelara®.

Can I get vaccinated during treatment with Stelara®?

You should not receive "live vaccinations", containing a live, weakened version of the virus, whilst receiving Stelara®. However, you may receive "non-live or

inactivated" vaccinations, in which the disease-causing virus or bacterium have been inactivated during the process of vaccine manufacturing.

Can I become pregnant during treatment with Stelara®?

There are insufficient data available about the use of Stelara® in pregnant women. If you are a woman of childbearing age, you must use an effective method of contraception during treatment and for 15 weeks after your last injection with Stelara®. Talk to your treating physician or nurse if you are pregnant, think you may be pregnant or are planning to have a baby. Talk to your treating physician or nurse if you are breastfeeding or are planning to breastfeed. You and your treating physician should decide if you should breastfeed or use Stelara® – do not do both.

What do I do if I get side effects with Stelara®?

For detailed information about possible side effects, please look at the corresponding section of this booklet ("Side effects that you may experience with Stelara®"). If you get any side effects listed here, please make sure you talk to your treating physician or nurse as soon as possible.

You can report any side effects via:

Website: <https://ade.sfda.gov.sa>

Email: npc.drug@sfda.gov.sa

Call center number: 19999

You can report side effects to Johnson & Johnson:

Website: <https://jniprd.agcloud.bz/LSM35/home.html>

Mailbox: GCC-PV2@its.jnj.com

Hotline: +966540015811



Glossary:

Biologic therapy: a type of therapy that uses substances made from living organisms (that either occur naturally or made in a laboratory) to treat disease

Immunosuppressants: a group of medicines that act by suppressing or dampening down the immune system

Immune system: A complex network of cells, tissues, organs, and the substances they make that helps the body fight infections and other diseases

Inactivated or non-live vaccinations: Inactivated or non-live vaccines contain whole bacteria or viruses which have been killed or have been altered, so that they cannot replicate

Intravenous infusion: a medical technique that delivers fluids directly into a person's vein, usually via a cannula (small tube)

Live vaccinations: vaccinations which contain a live, but weakened version of a virus

Monoclonal antibody: a type of protein made in the laboratory that can bind to substances in the body

Proteins: naturally occurring complex substances that play many critical roles in the body

Subcutaneous injection: a medical technique that administers a medication into the tissue layer between the skin and the muscle (under the skin), usually via a short needle

References:

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MY STELARA® TREATMENT GUIDE



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