

YOUR GUIDE TO UZPRUVO® ▼ (USTEKINUMAB)

FOR THE TREATMENT OF ULCERATIVE COLITIS

my Uzpruvo

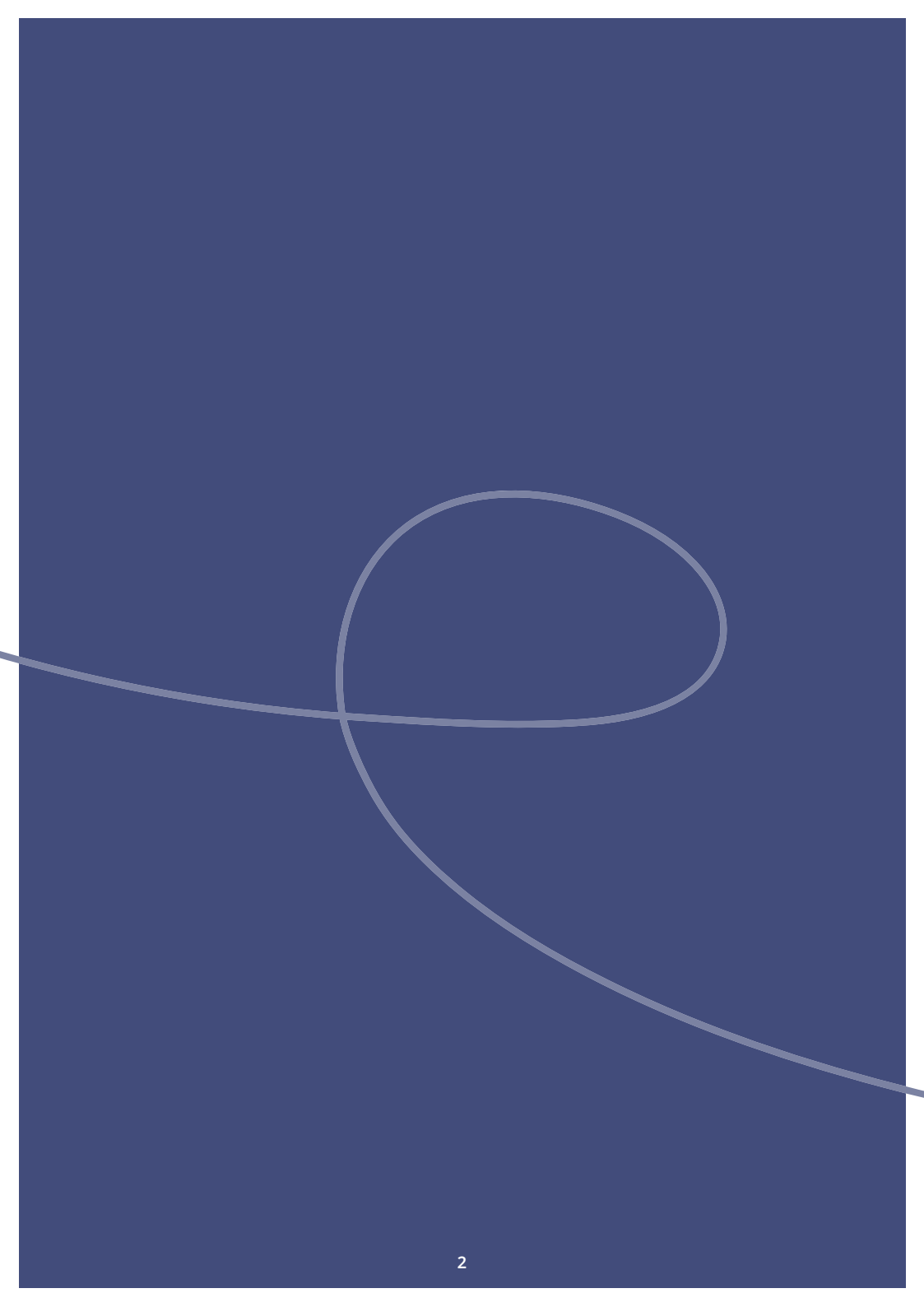


This guide is for patients who have been prescribed Uzpruvo. It is designed to support you with your treatment and is not a substitute for the Package Leaflet that came with your medication. For more information, visit uzpruvopatient.co.uk

Reporting of side effects. If you experience any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in the package leaflet. You can also report side effects directly via the Yellow Card Scheme at yellowcard.mhra.gov.uk or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects, you can help provide more information on the safety of this medicine.

This medicine is subject to additional monitoring. This will allow quick identification of new safety information. You can help by reporting any side effects you may experience. Visit yellowcard.mhra.gov.uk or search for MHRA Yellow Card in the Google Play or Apple App Store to see how to report side effects.

STADA
Specialty Care



Your guide

TO USING UZPRUVO® (USTEKINUMAB)

Uzpruvo® is a treatment for people with certain autoimmune diseases, including ulcerative colitis.¹ This guide contains information to support you in using Uzpruvo® and administering your medicine.



WHAT IS ULCERATIVE COLITIS?



WHAT IS A BIOSIMILAR?



GETTING STARTED WITH UZPRUVO®



HOW DO I USE UZPRUVO®?



HOW DO I STORE UZPRUVO®?



ADDITIONAL SUPPORT

WHAT IS ULCERATIVE COLITIS?^{2,3}

Ulcerative colitis is an autoimmune disease that causes inflammation and sores in your large intestine. It belongs to a group of conditions known as inflammatory bowel diseases, or IBD, and can develop at any age – although it is more likely to develop in people between the ages of 15 and 30. Ulcerative colitis may damage your intestine and your body may not be able to absorb enough nutrients to keep you nourished. The symptoms of ulcerative colitis vary from person to person and may include:

- Diarrhoea
- Passing blood, mucus or pus with your stool
- Cramping and pain in your belly
- A constant and/or urgent need to defecate
- Inability to defecate despite urgency with rectal pain
- Feeling tired and/or sick
- Fever
- Weight loss

Symptoms of ulcerative colitis may be constant, or may come and go every few weeks or months – when symptoms come back, it's called a 'flare-up'. There's no way to predict when flare-ups will happen.

WHAT CAUSES ULCERATIVE COLITIS?

Ulcerative colitis is complex and involves many factors, affecting about the same number of men and women. Ulcerative colitis can be triggered by a viral or bacterial infection; your immune system mistakes harmless bacteria as a threat and attacks the large intestine, causing it to become inflamed.

Ulcerative colitis seems to run in families, as it is more common in people who have relatives with the disease.² Common triggers include:^{3,4}

- Certain medications such as pain relievers and antibiotics
- Emotional stress

WHAT CAN I DO IF I HAVE BEEN DIAGNOSED WITH ULCERATIVE COLITIS?

Your doctor will make a treatment plan for you and provide you with all the necessary information you need. **Always take your medication as instructed by your doctor or nurse.** Your doctor may also recommend that you make changes to your diet to help reduce symptoms, such as:²



AVOID FIZZY DRINKS
AND ALCOHOL



AVOID HIGH-FIBRE FOODS
SUCH AS POPCORN,
VEGETABLE SKINS AND
NUTS



AVOID GREASY FOODS



AVOID HIGH-SUGAR
FOODS AND DRINKS



YOU SHOULD ALSO KEEP
A FOOD DIARY TO HELP
IDENTIFY FOODS THAT
CAUSE PROBLEMS

Your doctor may also recommend nutritional supplements and vitamins if you do not absorb enough nutrients. Always talk with your doctor or pharmacist before using dietary supplements.

WHAT IS A BIOSIMILAR?^{5,6}

A biosimilar is a biologic medicine that is highly similar to another biologic medicine which has already been approved (called the 'reference' medicine).

Biosimilars follow the same highly regulated approval process, but because much of the upfront development phase has already been completed for the reference medicine, they often cost less.

As a result, biosimilars can provide more people with access to an otherwise expensive therapy, while maintaining the same quality standards in terms of safety and efficacy.

Biosimilars have been in use as trusted medicines in Europe for

15+
YEARS⁷



86

biosimilars have been approved by the EMA (European Medicines Agency)⁷

UZPRUVO® IS AN USTEKINUMAB BIOSIMILAR¹

Uzpruvo® is a biosimilar medicine containing the same ingredient (ustekinumab) as the reference medicine. Like other biosimilars, Uzpruvo®:



Is approved according to the same standards that apply to all biologic medicines in Europe & the UK⁵⁻⁷



Has the same safety profile and efficacy as the reference medicine⁸



Helps enable increased access to ustekinumab treatment thanks to reduced cost burden⁹

IF YOU ARE CHANGING TREATMENT TO UZPRUVO® ...



... you shouldn't expect any changes in terms of safety or efficacy – the UK regulatory authority has confirmed that biosimilars and their reference products are **interchangeable**.^{5,6}

The administration of Uzpruvo® is also similar to that of the reference medicine, which you may already be familiar with.¹

GETTING STARTED WITH UZPRUVO®

Your doctor has prescribed Uzpruvo® to help treat your ulcerative colitis. Your doctor or pharmacist will show you how to use Uzpruvo® and let you know if they need to administer it or if you can do it yourself – if this happens, you will get training on how to administer Uzpruvo®. Talk to your doctor if you have any questions about giving yourself an injection and **do not administer Uzpruvo® yourself without discussing it with your doctor first.**

Your doctor or pharmacist will also provide you with a treatment plan explaining how often you need to take your medicine and the dose (how much medicine you should take). **Always use Uzpruvo® exactly as your doctor or pharmacist has prescribed and do not change the dose or stop the treatment unless they tell you to.** You can always check with them again if you have any questions.

It can help to set reminders to make administering Uzpruvo® easier for you. Here are some tips that can help you with this:

You may also find the **Uzpruvo® injection tracker** helpful to make note of your injections and stay on track. **This can be found inside this booklet.**

You have been prescribed Uzpruvo® by your doctor as a pre-filled syringe.



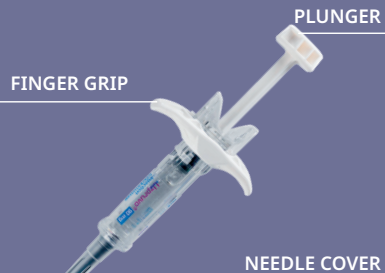
SET A REMINDER
ON YOUR PHONE
OR CALENDAR



PUT A NOTE
SOMEWHERE VISIBLE,
LIKE ON YOUR
FRIDGE

What if I miss a dose? If you miss a dose, contact your doctor or pharmacist. Do not take a double dose to make up for a forgotten dose

Uzpruvo® pre-filled syringe



Do not use Uzpruvo®

- If you are allergic to ustekinumab or any of the other ingredients of this medicine (see Package Leaflet for list of ingredients).
- If you have an active infection which your doctor thinks is important.

If you are not sure if any of the above applies to you, talk to your doctor or pharmacist before using Uzpruvo®.

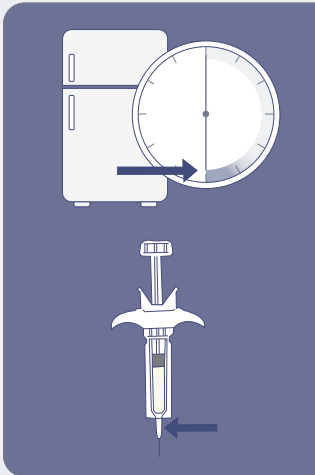
Warnings and precautions

Talk to your doctor or pharmacist before using Uzpruvo®. Your doctor will check how well you are before treatment. Make sure you tell your doctor about any illness you have before each treatment. Also tell your doctor if you have recently been near anyone who might have tuberculosis. Your doctor will examine you and do a test for tuberculosis, before you have Uzpruvo®. If your doctor thinks you are at risk of tuberculosis, you may be given medicines to treat it.

Look out for side effects

Uzpruvo® can cause side effects, including allergic reactions and infections. You must look out for certain signs of illness while you are taking Uzpruvo®. See 'Possible side effects' in the Package Leaflet or visit uzpruvopatient.co.uk/safety for a full list of these side effects.

HOW DO I USE UZPRUVO®?



STEP 1 – TAKE OUT OF REFRIGERATOR

Take Uzpruvo® out of the refrigerator and leave it at room temperature for approximately 30 minutes before injection.

DO NOT remove the grey needle cover from the pre-filled syringe

DO NOT use Uzpruvo® if the liquid has been frozen

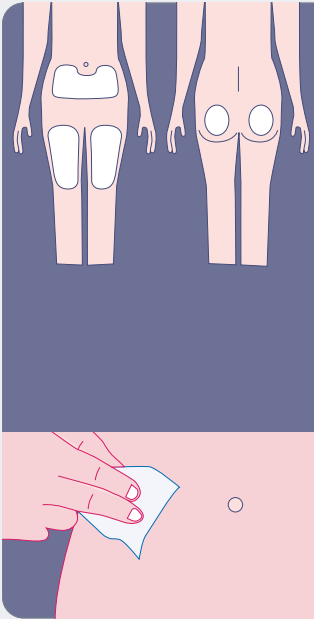
DO NOT shake the pre-filled syringe

DO NOT warm the pre-filled syringe in any other way (e.g. in hot water or in an oven or microwave)



STEP 2 – GET ITEMS READY

- Check Uzpruvo®: confirm it is the right medicine and dose strength, ensure it is not damaged and check the expiry date to make sure it is in date
- Confirm the solution in the syringe is clear and colourless to slightly yellow and practically free of visible particles
- Place the following items on a clean, flat surface:
 - Uzpruvo® pre-filled syringe
 - Antiseptic wipes
 - Adhesive bandage (not included in packaging)
 - Cotton balls or gauze pads (not included in packaging)
 - Puncture-resistant sharps disposal container (not included in packaging)
- Wash and dry your hands carefully with soap and warm water before injection

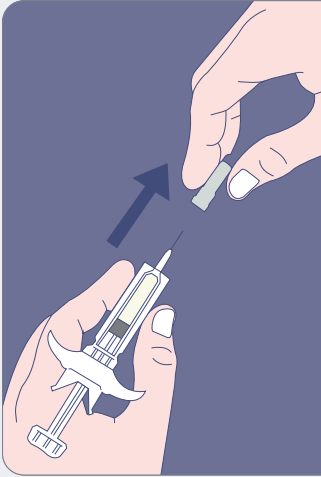


STEP 3 – CHOOSE AND CLEAN INJECTION SITE

- **Choose the injection site:** it can be on your upper thighs, buttocks or belly (at least 5 cm from your belly button). Do not give an injection in an area of skin that is sore, bruised, red or hard
- If you are administering two injections for the 90 mg dose, choose different injection sites (e.g. right thigh and left thigh)
- If a caregiver is giving you the injection, the outer area of the upper arms may also be used
- **Clean the skin with the antiseptic wipe** where you plan to give your injection and let it dry. Do not touch this area again before giving the injection and do not fan or blow on the clean area

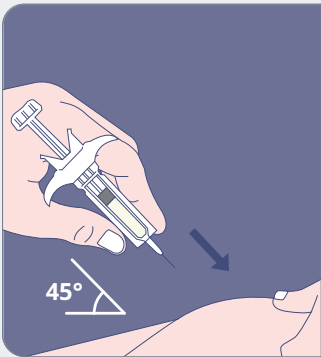
HOW DO I USE UZPRUVO®?

PRE-FILLED SYRINGE (45 mg and 90 mg)



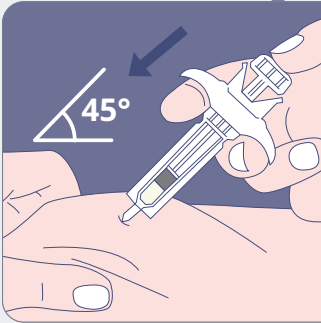
STEP 4 – REMOVE THE NEEDLE COVER

- Hold the body of pre-filled syringe with one hand, and pull the needle cover straight off with the other. Do not touch the plunger while removing the needle cover
- Throw the needle cover away and do not recap the pre-filled syringe. Be careful not to touch the needle or let it touch anything
- You may see a drop of liquid at the end of the needle. This is normal
- Inject the dose promptly after removing the needle cover



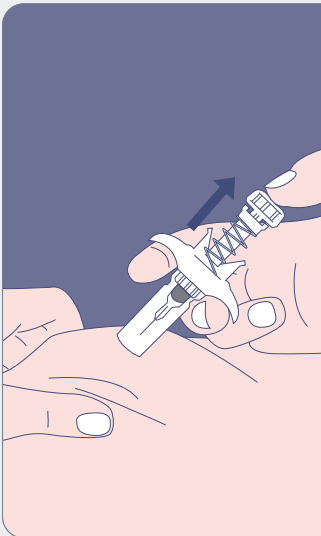
STEP 5 – GRASP THE SYRINGE AND PINCH THE SKIN

- Hold the body of the pre-filled syringe in one hand between the thumb and index finger, as shown in the image. Be careful not to pull back on the plunger at any time
- Use the other hand to gently pinch the area of cleaned skin at the injection site and hold it firmly



STEP 6 – INJECT UZPRUVO®

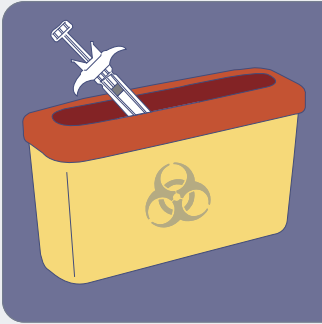
- Use a quick, dart-like motion to insert the needle into the pinched skin at an angle of about 45°. Once the needle is in, let go of the skin
- Slowly push the plunger all the way in until all the liquid has been injected and the pre-filled syringe is empty



STEP 7 – REMOVE NEEDLE FROM SKIN

- When the plunger is pushed as far as it will go, keep pressure on the plunger head. Take the needle out of the skin and let go of the skin
- Slowly take your thumb off the plunger head. The plunger will move up with your finger and retract the needle into the needle guard
- After completing the injection, place a cotton ball or gauze pad on the skin at the injection site for a few seconds without rubbing
- There may be slight bleeding at the injection site. This is normal
- If necessary, you can cover the injection site with a small adhesive bandage

HOW DO I THROW THE UZPRUVO® PRE-FILLED SYRINGE AWAY?



- Dispose in **sharps disposal container:**
Uzpruvo® pre-filled syringes and any other sharps
- Dispose in **normal household waste:**
Needle cover, antiseptic wipe, cotton ball or gauze pad and packaging

HOW DO I STORE UZPRUVO®?



Store in a refrigerator (2–8°C). Do not freeze



If unopened and kept in a refrigerator at 2–8°C, Uzpruvo® can be stored until the expiry date printed on the carton



Do not use Uzpruvo® after the expiry date. The expiry date is written on the packaging and refers to the last day of that month



Protect from light by keeping in outer carton until use



Keep Uzpruvo® out of sight and reach of children



When needed (for example, when the patient is travelling), individual Uzpruvo® pre-filled syringes may be stored at a temperature of up to 30°C in the original carton for a **maximum period of 30 days**.

- Store in the original carton in order to protect from light
- Once removed from the refrigerator, record the discard date in the space provided on the outer carton
- The discard date must not exceed the original expiry date printed on the carton
- **DO NOT** return syringe to the refrigerator
- Discard the syringe **if not used within 30 days** at room temperature storage or by the original expiry date, whichever is earlier

Please read the complete Uzpruvo® Package Leaflet before use. Speak to your doctor or pharmacist if you:

- Have any questions about Uzpruvo® or your treatment plan
- Experience any side effects: this includes any possible side effects that are not listed in the Uzpruvo® Package Leaflet

You should also report side effects directly, using the instructions provided below.

REPORTING OF SIDE EFFECTS

Reporting of side effects. If you experience any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in the package leaflet. You can also report side effects directly via the Yellow Card Scheme at yellowcard.mhra.gov.uk or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects, you can help provide more information on the safety of this medicine.

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HOME CARE SERVICE

The Homecare Service delivers your treatment to your home or another address more convenient for you. You choose the day and time too, to make sure delivery fits your plans. It's important to remember the homecare service is for the supply of your medicine only. You should still attend all clinic appointments. If you have any questions about the Homecare service you can email us at the following address: homecare@thorntonross.com.

You will be allocated to one of these Homecare companies by your doctor or nurse:



HealthNet Homecare
healthnethomecare.co.uk
Phone: 0800 083 3060

LloydsPharmacy

**Clinical
Homecare**

**Lloyds Pharmacy
Clinical Homecare**
lpclinicalhomecare.co.uk
Phone: 0345 263 6123
(England and Wales)
Phone: 0345 263 6135
(Northern Ireland and Scotland)



Sciensus
sciensus.com
Phone: 0333 1039 499

References. **1.** Uzpruvo SmPC. Available at <https://www.medicines.org.uk/emc/search?q=Uzpruvo>. Last accessed: October 2024. **2.** Mayo Clinic. September 2022. Ulcerative colitis. Available at: <https://www.mayoclinic.org/diseases-conditions/ulcerative-colitis/symptoms-causes/syc-20353326>. Last accessed: October 2024. **3.** Cleveland Clinic. May 2023. Ulcerative colitis. Available at: <https://my.clevelandclinic.org/health/diseases/10351-ulcerative-colitis>. Last accessed: October 2024. **4.** National Health Service (NHS). November 2022. Ulcerative colitis. Available at: <https://www.nhs.uk/conditions/ulcerative-colitis/>. Last accessed: October 2024. **5.** NHS England, Biosimilar medicines. Available at: <https://www.england.nhs.uk/medicines-2/biosimilar-medicines/>. Last accessed: October 2024. **6.** UK Government. Guidance on the licensing of biosimilar products. Available at: <https://www.gov.uk/government/publications/guidance-on-the-licensing-of-biosimilar-products/guidance-on-the-licensing-of-biosimilar-products>. Last accessed: October 2024. **7.** EMA, Biosimilar medicines can be interchanged. Available at: <https://www.ema.europa.eu/en/news/biosimilar-medicines-can-be-interchanged>. Last accessed: October 2024. **8.** Feldman SR et al. Expert Opin Biol Ther. 2023;23(3):253-60. DOI: 10.1080/14712598.2023.2235263. **9.** Cost of Uzpruvo and reference product taken from NHS DM+D. Available at: <https://dmd-browser.nhsbsa.nhs.uk>. Last accessed: October 2024.