Made for us

UZPRUVO®▼ (USTEKINUMAB)
DOSING & ADMINISTRATION

This guide is for UK healthcare professionals only

Adverse events should be reported. Reporting forms and information can be found at yellowcard.mhra.gov.uk or search for MHRA Yellow Card in the Google Play or Apple App Store. Adverse events should also be reported to Thornton and Ross Limited by emailing thorntonross@medinformation.co.uk or by calling 01484 848164.

Always read the Summary of Product Characteristics (SmPC) before administration.
Prescribing information is available on the **back cover.**

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Specialty Care

WELCOME TO UZPRUVO®

This guide has been designed to support UK healthcare professionals with dosing, administration and storage of Uzpruvo. Always read the Summary of Product Characteristics (SmPC) before administration.

WHO SHOULD BE GIVEN UZPRUVO®?[1]

Uzpruvo® is an ustekinumab biosimilar from STADA approved for the treatment of:

Plaque psoriasis: Adults with moderate to severe plaque psoriasis who failed to respond to, or who have a contraindication to, or are intolerant to other systemic therapies including ciclosporin, methotrexate (MTX) or psoralen and ultraviolet A (PUVA).[1]

Paediatric plaque psoriasis: Uzpruvo is indicated for the treatment of moderate to severe plaque psoriasis in children and adolescent patients from the age of 6 years and older, who are inadequately controlled by, or are intolerant to, other systemic therapies or phototherapies.[1]

Psoriatic arthritis: Adult patients with active psoriatic arthritis, alone or in combination with MTX, when the response to previous non-biological disease-modifying anti-rheumatic drug (DMARD) therapy has been inadequate.[1]

Crohn's disease: Adult patients with moderately to severely active Crohn's disease who have had an inadequate response with, or lost response to, or were intolerant to either conventional therapy or a tumour necrosis factor.[1]

Ulcerative colitis: Adult patients with moderately to severely active ulcerative colitis who have had an inadequate response with, lost response to, or were intolerant to either conventional therapy or a biologic or have medical contraindications to such therapies.[1]

WHO SHOULD ADMINISTER UZPRUVO®?[1]

Uzpruvo® is a prescription only medicine and should be given under the guidance and supervision of a doctor experienced in diagnosing and treating the conditions for which Uzpruvo® is indicated. Patients may self-inject with Uzpruvo® subcutaneously with their doctor's approval and appropriate training. Depending on the indication, an initial IV infusion of Uzpruvo® may be required: this will always be administered by a healthcare professional and can't be self-injected.

Contraindications. Hypersensitivity to the active substance or to any of the excipients. Clinically important, active infection (e.g. active tuberculosis).

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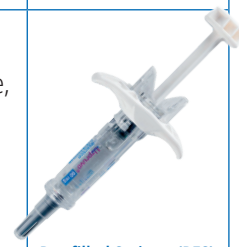
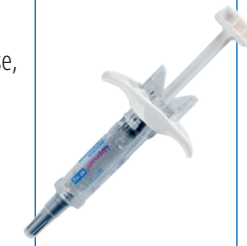
HOW IS UZPRUVO® USED?[1]

For further information on dosing, please refer to the Summary of Product Characteristics.

Indication	Induction dose	Maintenance dose	Presentation
Moderate to severe Crohn's disease in adults and Moderate to severe active ulcerative colitis in adults	**Initial intravenous dosing** The approved ustekinumab treatment regimen for patients with Crohn's disease and ulcerative colitis is initiation with a single IV dose based on body weight. The infusion solution is to be composed of the number of vials of Uzpruvo 130 mg as specified below. Each 26 mL vial of Uzpruvo contains 130 mg of ustekinumab. **Body Weight:** / **Dose:** ≤55 kg / 260 mg > 55 kg to ≤ 85 kg / 390 mg > 85 kg / 520 mg	**SC injection via PFS:** **90 mg** • 8 weeks after induction dose, then Q12W • Q8W if inadequate response	 130mg vial and Pre-filled Syringe (PFS)
Moderate to severe plaque psoriasis and active psoriatic arthritis in adults	**SC injection via PFS at Week 0 and 4** **Body Weight:** / **Dose:** ≤100 kg / 45 mg >100 kg / 90 mg	**SC injection via PFS:** • Same as induction dose, Q12W	 Pre-filled Syringe (PFS)
Moderate to severe paediatric plaque psoriasis (≥6 years)	**SC injection via PFS at Week 0 and 4** **Body Weight:** / **Dose:** ≥60 to ≤100 kg / 45 mg >100 kg / 90 mg Currently there is no dosage form for Uzpruvo that allows weight-based dosing for paediatric patients below 60 kg. In these situations an alternative ustekinumab product should be used.	**SC injection via PFS:** • Same as induction dose, Q12W	 Pre-filled Syringe (PFS)

Tip for training patients: Remind patients to always take Uzpruvo® exactly as instructed and not to change the dose or stop the treatment unless their doctor tells them to. In case of a missed dose, patients should contact their pharmacist or doctor for further advice and not take a double dose to make up for the forgotten one.

IV, intravenous; PFS pre-filled syringe, Q8W, every 8 weeks; Q12W, every 12 weeks; SC subcutaneous

ADMINISTERING UZPRUVO® VIA INTRAVENOUS INFUSION USING THE 130 mg VIAL

An initial IV infusion of Uzpruvo® is indicated for moderate to severe Crohn's disease in adults and moderate to severe active ulcerative colitis in adults.[1]

This must always be administered by a healthcare professional and can't be self-injected. Uzpruvo® concentrate for solution for infusion should only be used for the intravenous induction dose. Use an aseptic technique to dilute, prepare and infuse the Uzpruvo® solution for infusion.

Dilution instructions for Uzpruvo® 130mg vial

1. Calculate the dose and the number of Uzpruvo® vials needed based on patient weight (see table opposite).

2. Withdraw and then discard 26 mL of the sodium chloride 9 mg/mL (0.9%) solution from the 250 mL infusion bag for each vial of Uzpruvo® needed (e.g. discard 52 mL sodium chloride for 2 vials).

3. Withdraw 26 mL of Uzpruvo® from each vial to be used and add it to the 250 mL infusion bag so the final volume becomes 250 mL. Gently mix.

4. Visually inspect the diluted solution before administration. Do not use if visibly opaque particles, discolouration or foreign particles are observed.

5. Infuse the diluted solution over a period of at least one hour. Once diluted, the infusion should be completed within eight hours of the dilution in the infusion bag:

> **Only use an infusion set with an in-line, sterile, non-pyrogenic, low protein-binding filter (pore size 0.2 µm)**

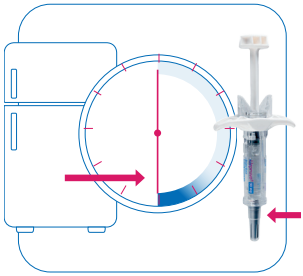
Storage and shelf-life for Uzpruvo® 130mg vial

- Store in a refrigerator at 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.
- Protect from light by keeping in the outer carton until use.
- Uzpruvo® 130mg vial shelf life: 18 months
- Chemical and physical in-use stability has been demonstrated for 8 hours at 15-25°C

> **From a microbiological point of view, unless the method of dilution precludes the risk of microbial contamination, the product should be used immediately. If not used immediately, in-use storage times and conditions are the responsibility of user.**

> **Each vial is for single use only and any unused Uzpruvo® should be disposed of in accordance with local requirements.**

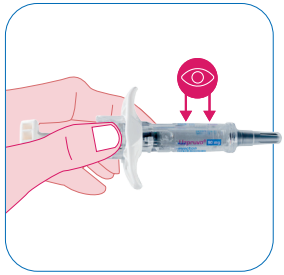
ADMINISTERING UZPRUVO®
PRE-FILLED SYRINGE (45 mg AND 90 mg)



1. Take out of refrigerator[1]

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

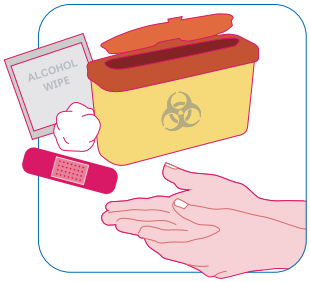
- **DO NOT** remove the grey needle cover from the pre-filled syringe
- **DO NOT** use Uzpruvo® if the liquid has been frozen
- **DO NOT** shake the pre-filled syringe
- **DO NOT** warm the pre-filled syringe in any other way (e.g. in hot water or in an oven or microwave)



2. Get items ready[1]

Check and confirm:

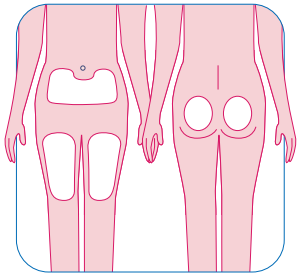
- It is the right medicine and dose strength, ensure it is not damaged and check the expiry date to make sure it is in date
- The solution should be clear and colourless to slightly yellow and free of visible particles

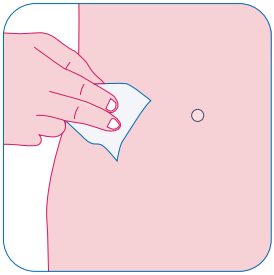


Place the following items on a clean, flat surface:

- 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 before injection





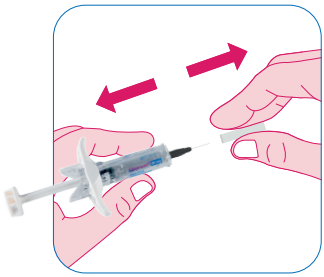
3. Choose and clean the injection site[1]

Select the injection site:

- It can be on the upper thighs, buttocks or abdomen (at least 5 cm from the navel). Do not give an injection in an area of skin that is tender, bruised, red or hard
- If two injections are being administered for the 90 mg dose, different injection sites should be used (e.g. right thigh and left thigh)
- If you are assisting in giving the injection, the upper arms may also be used as an injection site

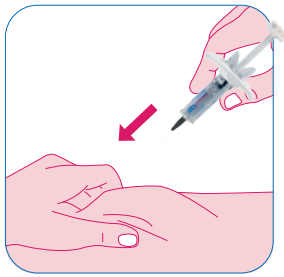
Clean the injection site with the antiseptic wipe

- Let it dry naturally before injecting.
- **DO NOT** blow or fan the area
- **DO NOT** touch this area again before giving the injection



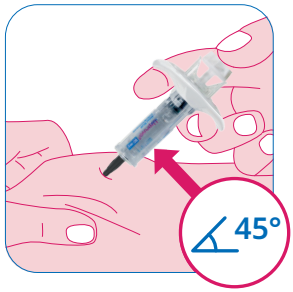
4. Remove the needle cover[1]

- 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



5. Grasp the syringe and pinch the skin[1]

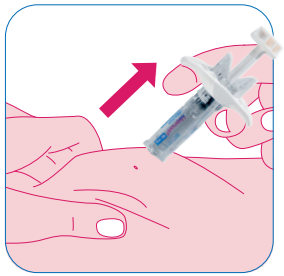
- Hold the body of the pre-filled syringe in one hand between the thumb and index finger. Be careful not to pull back on the plunger at any time
- With the other hand, gently pinch the area of cleaned skin at the injection site and hold it firmly



6. Inject Uzpruvo®[1]

- Insert the needle into the skin at an angle of about 45° using a quick, dart-like motion. 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
- **DO NOT** inject through clothes

Ensure the pre-filled syringe is completely empty!

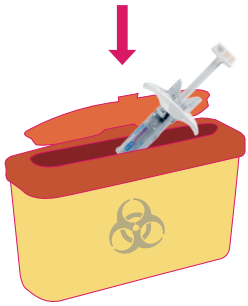


7. Remove needle from skin[1]

- Keeping pressure on the plunger head, take the needle out of the skin and let go of the skin
- Slowly lift your finger from the plunger, let it move up and retract the needle into the needle guard. Please note that the needle will not retract into the syringe unless all the liquid has been injected
- After completing the injection, place a cotton ball or gauze pad on the skin at the injection site for a few seconds without rubbing
- If necessary, you can cover the injection site with a small adhesive bandage

Tip for training patients:
Remind patients that slight bleeding at the injection site is normal

DISPOSING OF UZPRUVO® PRE-FILLED SYRINGE[1]



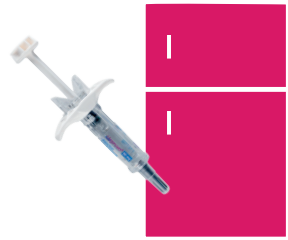
Dispose in sharps disposal container:

- Uzpruvo® pre-filled syringes
- Any other sharps

Dispose in normal household waste:

- Needle cover
- Antiseptic wipe
- Cotton ball or gauze pad
- Packaging

STORAGE & SHELF LIFE FOR UZPRUVO® PRE-FILLED SYRINGE



- Store in a refrigerator at 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
- Protect from light by keeping in the outer carton until use
- Uzpruvo pre-filled syringe shelf life: 3 years

How long can Uzpruvo® be stored at room temperature (e.g. when travelling)?[1]

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

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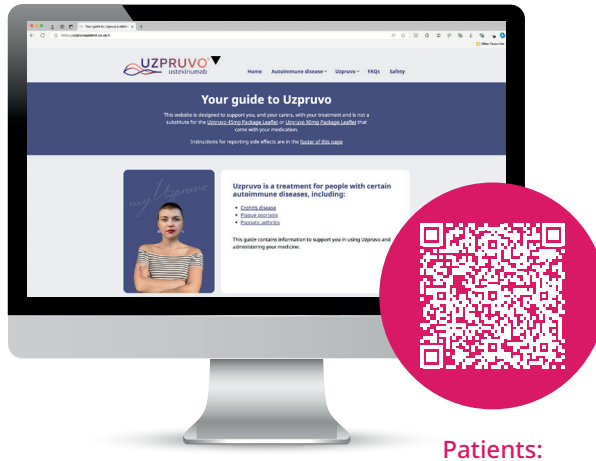
SUPPORT MATERIALS

Comprehensive support materials for both patients and healthcare professionals (including an application video) are available on our dedicated web sites:

Healthcare professionals:
stadaspecialtybiosimilars.co.uk/uzpruvo



Patients:
uzpruvopatient.co.uk

Prescribing Information for:

▼ Uzpruvo 45 mg, 90 mg solution for injection in pre-filled syringe, Uzpruvo 130 mg concentrate for solution for infusion.

Please refer to the Summary of Product Characteristics before prescribing Uzpruvo.

Presentation: Each pre-filled syringe contains either 45 mg ustekinumab in 0.5 mL or 90 mg ustekinumab in 1 mL. Each vial contains 130 mg ustekinumab in 26 mL (5 mg/mL).

Indications: ***Uzpruvo 45 mg, 90 mg:*** Treatment of plaque psoriasis in adults who failed to respond to, have a contraindication to or are intolerant to other systemic therapies. Moderate to severe plaque psoriasis in children from the age of 6 years who are inadequately controlled by, or intolerant to other systemic therapies or phototherapies. ***Uzpruvo 45 mg, 90 mg:*** Active psoriatic arthritis (PsA) in adults when response to non-biological disease-modifying anti-rheumatic drug (DMARD) therapy has been inadequate. ***Uzpruvo 45 mg, 90 mg, 130mg:*** Treatment of moderate to severe Crohn's disease in adults who have an inadequate response with, lost response to, or were intolerant to either conventional therapy or a TNFαantagonist or have medical contraindications to such therapies. ***Uzpruvo 45 mg, 90 mg, 130mg:*** Treatment of moderate to severe ulcerative colitis in adults who have had an inadequate response with, lost response to, or were intolerant to either conventional therapy or a biologic or have medical contraindications to such therapies.

Dosage and administration: Use under the guidance and supervision of physicians experienced in the diagnosis and treatment of the indicated conditions. ***Plaque psoriasis:*** Initial dose of 45 mg administered subcutaneously, followed by a 45 mg dose 4 weeks later, and then every 12 weeks thereafter. ***PsA:*** Initial dose of 45 mg administered subcutaneously, followed by a 45 mg dose 4 weeks later, and then every 12 weeks thereafter, alternatively, 90 mg may be used in patients with a body weight > 100 kg. ***Paediatric plaque psoriasis (6 years and older):*** Dose is based on body weight ≥ 60 kg. See SmPC before prescribing. Uzpruvo should be administered at weeks 0 and 4, then every 12 weeks thereafter. ***Crohn's disease and ulcerative colitis (Adults):*** Treatment should be initiated by intravenous infusion based on body weight. The first subcutaneous administration of 90 mg should take place at week 8 after the intravenous dose. Thereafter, dosing every 12 weeks is recommended. Patients may be dosed every 8 weeks or every 12 weeks according to clinical judgment. Discontinuing treatment may be considered in patients who show no evidence of therapeutic benefit 16 weeks after the IV induction dose or 16 weeks after switching to the 8-weekly maintenance dose. Immunomodulators and/or corticosteroids may be continued during treatment with Uzpruvo. In responsive patients, corticosteroids may be reduced or discontinued in accordance with standard of care. See SmPC before prescribing. ***Method of administration: Uzpruvo 130 mg:*** Intravenous use only, administered over at least 1 hour. ***Uzpruvo 45 mg, 90 mg:*** Subcutaneous injection only.

Contraindications: Hypersensitivity to the active substance or to any of the excipients. Clinically important, active infection.

Warnings and Precautions: Ustekinumab may have the potential to increase the risk of infections and reactivate latent infections. Opportunistic infections have been reported. Caution should be exercised in patients with chronic infection or history of recurrent infection. Patients should be evaluated for tuberculosis infection before, during and after treatment. Immunosuppressants have the potential to increase the risk of malignancy. The risk may be higher in psoriasis patients previously treated with biologics. All patients, in particular those greater than 60 years, patients with a medical history of prolonged immunosuppressant therapy or those with a history of PUVA treatment, should be monitored for the appearance of non-melanoma skin cancer. Serious hypersensitivity reactions including anaphylaxis and angioedema have occurred. Allergic alveolitis, eosinophilic pneumonia, and non-infectious organising pneumonia have been reported. In patients with psoriasis exposed to ustekinumab cardiovascular events including myocardial infarction and cerebrovascular accident have been observed. Live viral or live bacterial vaccines should not be given concurrently with Uzpruvo. In patients with psoriasis, exfoliative dermatitis has been reported. Patients with plaque psoriasis may develop erythrodermic psoriasis. Lupus-related conditions have been reported. Due to higher incidence of infections in the elderly, use with caution in these patients.

Pregnancy and lactation: Women of childbearing potential should use effective methods of contraception during treatment and for at least 15 weeks after treatment. ***Pregnancy:*** Avoid the use of Uzpruvo in pregnancy. ***Breast-feeding:*** Ustekinumab is excreted in breast milk, risk to the breastfed infant cannot be excluded.

Undesirable effects: ***Serious side effects:*** Cellulitis, herpes zoster, serious hypersensitivity reactions, anaphylaxis, angioedema, organising pneumonia, eosinophilic pneumonia, exfoliative dermatitis, bullous pemphigoid, erythrodermic psoriasis, hypersensitivity vasculitis, myocardial infarction, cerebrovascular accident, lupus-like syndrome, cutaneous lupus erythematosus. ***Common side effects:*** Upper respiratory tract infection, nasopharyngitis, sinusitis, dizziness, headache, oropharyngeal pain, diarrhoea, nausea, vomiting, pruritus, back pain, myalgia, arthralgia. For full list of side effects, consult SmPC.

Legal Category: POM

Pack size and price: Solution for injection in pre-filled syringe - 1 x 45 mg (£1,932.30), 1 x 90 mg (£1,932.30). Concentrate for solution for infusion 1 x 130 mg vial (£1,932.30)

MA Number: PLGB 17225/0022, PLGB 17225/0023, PLGB 17225/0025

MA Holder: Genus Pharmaceuticals Holdings Limited (trading as STADA), Linthwaite, Huddersfield, HD7 5QH, UK

Date of preparation: October 2024

Unique ID number: UK-Uzpru-9(2)a(1)

Adverse events should be reported. Reporting forms and information can be found at yellowcard.mhra.gov.uk or search for MHRA Yellow Card in the Google Play or Apple App Store. Adverse events should also be reported to Thornton and Ross Limited by emailing thorntonross@medinformation.co.uk or by calling 01484 848164.

References:

1. Uzpruvo SmPC. Available at https://www.medicines.org.uk/emc/search?q=Uzpruvo. Last accessed: November 2024.

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