Made for us

*Fictional patients

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.

This document is for UK healthcare professionals only. Always read the Summary of Product Characteristics (SmPC) before administration. Prescribing information is available on the back cover.

STADA

Thornton & Ross
STADA GROUP

UZPRUVO INDICATIONS

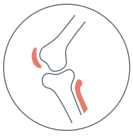
Uzpruvo is available in a 130mg vial for intravenous use and as a 45 mg or 90 mg solution in a prefilled syringe for subcutaneous injection.[1]

Plaque psoriasis[1]

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[1]

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]

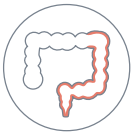


Psoriatic arthritis[1]

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[1]

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[1]

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]

WHY SHOULD BIOSIMILARS BE USED?

According to NHS England, biosimilars should be used because they offer the same clinical effectiveness and safety as their reference products, but usually at substantially lower cost.[3] The EMA and HMA have released a joint statement explaining that once a biosimilar is approved in the EU it is interchangeable, which means it can be used instead of its reference product[4]

INTRODUCING UZPRUVO

Uzpruvo is the new ustekinumab biosimilar from STADA, offering you and your patients a number of benefits:

Cost-effective option enabling improved access to ustekinumab treatment[1,5]

Manufactured in Iceland and packaged in the United Kingdom

STADA supply chain excellence with service levels exceeding 95% throughout 2022[§,6]

Three homecare partners offering flexible delivery and nurse support for your patients (HealthNet, LPCH and Sciensus)

Patient-friendly pre-filled syringe: easy handling, thinner needle than the reference product[†,7,8] & latex-free plunger stopper[‡,1]

Equivalent efficacy, safety and immunogenicity to the reference product[*,2]

Full range of patient support materials including booklets, homecare guides, web site and video

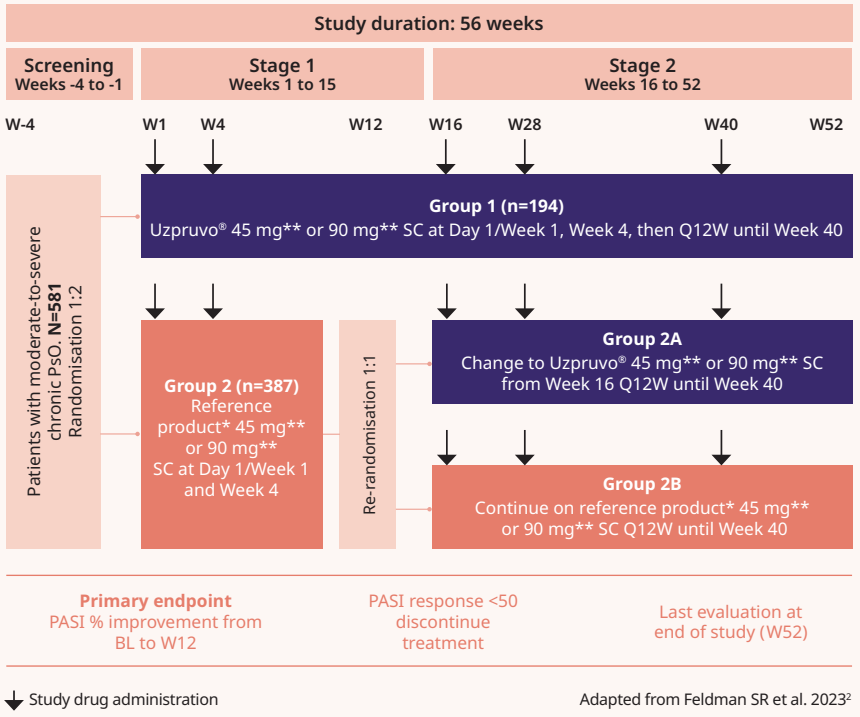
[§] Supply chain is constantly being optimised and manufacturing location is subject to change; * Stelara®; [†]29 vs 27-gauge needle of the reference product, Stelara®[7]; [‡]Plunger stopper made of bromobutyl rubber[1]

Visit **stadaspecialtybiosimilars.co.uk/uzpruvo** for more

(web site may contain promotional content)

SIMILAR EFFICACY, SAFETY AND PHARMACOKINETIC PROFILE, EVEN AFTER TREATMENT CHANGE TO UZPRUVO[2]

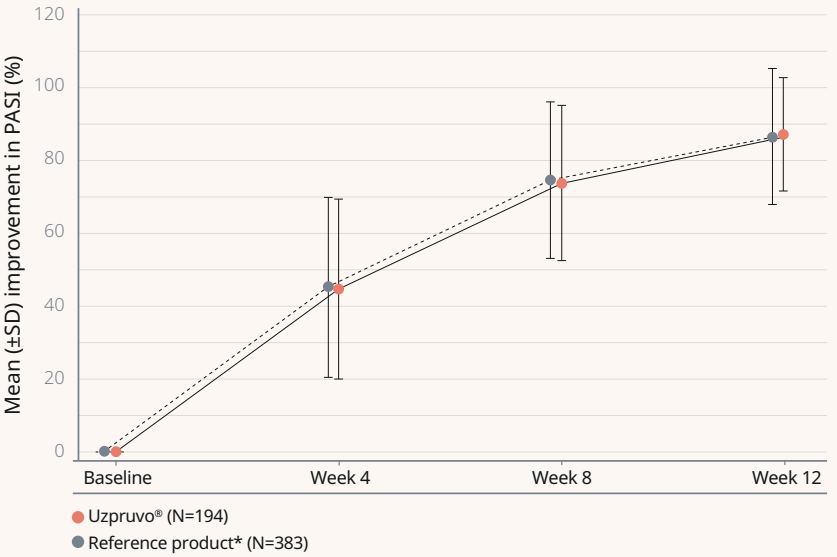
Study design: Phase III, multicentre, double-blind, randomised, parallel, active controlled study of Uzpruvo compared with reference product* in patients with moderate-to-severe chronic plaque psoriasis[2]



Adapted from Feldman SR et al. 2023[2]

The study primary endpoint was met: the percent improvement in PASI (Psoriasis Area and Severity Index) from baseline to Week 12 for Uzpruvo (87.3%) and the reference product* (86.8%) were similar[2]

Improvement in PASI from baseline up to Week 12†2



*Stelara®; The 90% CI (-2.14, 3.01) and 95% CI (-2.63, 3.50) for the primary endpoint were within the equivalence margins[2]; †Demonstrated in a Phase III clinical study of patients with moderate to severe chronic plaque psoriasis.[2]
Adapted from Feldman SR et al. 2023.[2]

Patients receiving Uzpruvo had similar improvement in PASI (Psoriasis Area and Severity Index) compared to patients who received the reference product* from Weeks 16–52, even after treatment change to Uzpruvo.[2]

- Similar efficacy†2
- Similar safety profile and frequency of TEAEs†2
- Similar immunogenicity profile†2

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)

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CI, confidence interval; **EMA**, European Medicines Agency; **HMA**, Heads of Medicines Agencies; **IV**, intravenous; **PASI**, Psoriasis Activity Severity Index; **PFS**, pre-filled syringe; **Q8W**, every 8 weeks; **Q12W**, every 12 weeks; **SC**, subcutaneous; **SD**, standard deviation; **TEAE**, treatment-emergent adverse event; **W**, week.

References: 1. Uzpruvo® SmPC available at: https://www.medicines.org.uk/emc/search?q=Uzpruvo last accessed October 2024; **2.** Feldman SR et al. Expert Opin Biol Ther. 2023;23(3):253-60. DOI: 10.1080/14712598.2023.2235263; **3.** NHS England. What is a biosimilar medicine? Last updated 21 February 2023. Available at: https://www.england.nhs.uk/long-read/what-is-a-biosimilar-medicine/ Last accessed: October 2024. **4.** European Medicines Agency. Statement on the scientific rationale supporting interchangeability of biosimilar medicines in the EU. Available at: https://www.ema.europa.eu/en/documents/public-statement/statement-scientific-rationale-supporting-interchangeability-biosimilar-medicines-eu_en.pdf last accessed October 2024; **5.** Cost of Uzpruvo and reference product taken from NHS DM+D. Available at: https://dmd-browser.nhsbsa.nhs.uk. Accessed October 2024. **6.** STADA | Press Release 06/03/2023. Available at: https://www.stada.com/blog/posts/2023/march/stada-sustains-strong-momentum-with-double-digit-sales-and-profit-growth-in-2022. Last accessed: October 2024. **7.** Stelara package insert. Available at: https://www.janssenlabels.com/package-insert/product-monograph/prescribing-information/STELARA-pi.pdf. Last accessed October 2024; **8.** Jaber A, Bozzato GB, Vedrine L, Prais WA, Berube J, Laurent PE. A novel needle for subcutaneous injection of interferon beta-1a: effect on pain in volunteers and satisfaction in patients with multiple sclerosis. BMC Neurol. 2008 Oct 10;8:38. doi: 10.1186/1471-2377-8-38. PMID: 18845005; PMCID: PMC2577094. Available at: https://pubmed.ncbi.nlm.nih.gov/18845005/. Last accessed: October 2024.