STADA
Specialty Care

UZPRUVO®
ustekinumab

Uzpruvo®▼(ustekinumab) Homecare Offering Guide

For UK Healthcare Professionals only. Prescribing Information and Adverse Events can be found overleaf.
Always read the Summary of Product Characteristics (SmPC) before administration.

UZPRUVO®▼ is STADA's ustekinumab biosimilar and offers a cost-effective alternative to the reference product.[1,2]

UZPRUVO®▼(ustekinumab) is indicated for the treatment of moderate to severe Crohn's disease in adults, moderate to severe plaque psoriasis in adults, moderate to severe paediatric plaque psoriasis and psoriatic arthritis in adults.[1]

Uzpruvo® is currently not approved for the Ulcerative Colitis indication (since the originator still has exclusivity for this indication)

UZPRUVO® is available as either 45 mg and 90 mg solution for injection in pre-filled syringe for subcutaneous use.[1]

Three Homecare Companies

All offering flexible delivery and nurse support for your patients:

LloydsPharmacy Clinical Homecare

www.lpclinicalhomecare.co.uk
Phone:
0345 263 6123 (England and Wales)
0345 263 6135 (Northern Ireland and Scotland)

Sciensus

www.sciensus.com
Phone:
0333 1039 499

HealthNet Homecare

www.healthnethomecare.co.uk
Phone:
0800 083 3060
HCP support:
client.services@healthnethomecare.co.uk

Transition Roadmap

The transition process is designed to flow swiftly and effectively, taking no more than 5 working days between each step.

Initial registration → 5 working days → **First delivery** → 5 working days → **First nurse visit**

Support

Pharmacist support from a dedicated Homecare Account Manager within STADA UK, Thornton and Ross, to help and support with any Homecare queries. homecare@thorntonross.com

For further details please see the Uzpruvo® website

Why choose Uzpruvo®?

The Uzpruvo® pre-filled syringe has been designed as a comparative device to the originator, allowing for a seamless transition.

Cost-effective option enabling improved access to ustekinumab treatment[1,2]

European manufacturing[1]and supply chain with supply service levels exceeding 95% throughout 2022[†3]

Equivalent efficacy, safety and immunogenicity to the reference product[††4]

Prescribing Information

▼ **Uzpruvo 45 mg solution for injection in pre-filled syringe.**

▼ **Uzpruvo 90 mg solution for injection in pre-filled syringe.**

Please refer to the Summary of Product Characteristics before prescribing Uzpruvo

Presentation: Each 45 mg pre-filled syringe contains 45 mg ustekinumab in 0.5 mL. Each 90 mg pre-filled syringe contains 90 mg ustekinumab in 1 mL.

Indications: Treatment of moderate to severe 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. Active psoriatic arthritis (PsA) in adults when response to non-biological disease-modifying anti-rheumatic drug (DMARD) therapy has been inadequate. 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 TNF ***α*** antagonist 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. ***Psoriatic arthritis (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 see SmPC for the recommended dose, Uzpruvo should be administered at weeks 0 and 4, then every 12 weeks thereafter. ***Crohn's disease*** - treatment of CD should be initiated by intravenous infusion, another ustekinumab product must be used as first intravenous dose (130 mg concentrate for solution for infusion). The first subcutaneous administration of 90 mg Uzpruvo should take place at week 8 after the intravenous dose. After this, dosing every 12 weeks is recommended. ***Method of administration*** - subcutaneous injection only.

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

Warnings and Precautions: ***Infections*** - ustekinumab may have the potential to increase the risk of infections and reactivate latent infections. Opportunistic infections including reactivation of tuberculosis, other opportunistic bacterial infections, opportunistic fungal infections, opportunistic viral infections, and parasitic infections have been reported. ***Malignancies*** – immunosuppressants have the potential to increase the risk of malignancy. 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. ***Systemic and respiratory hypersensitivity reactions – systemic,*** serious hypersensitivity reactions including anaphylaxis and angioedema have occurred. ***Respiratory,*** allergic alveolitis, eosinophilic pneumonia, and non-infectious organising pneumonia have been reported. ***Cardiovascular events*** - in patients with psoriasis exposed to ustekinumab cardiovascular events including myocardial infarction and cerebrovascular accident have been observed. ***Vaccinations*** - live viral or live bacterial vaccines should not be given concurrently with Uzpruvo. ***Serious skin conditions*** - in patients with psoriasis, exfoliative dermatitis has been reported.

Patients with plaque psoriasis may develop erythrodermic psoriasis. ***Lupus-related conditions*** - lupus-related conditions have been reported.

Fertility, 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. ***Fertility*** - effect on fertility is unknown.

Undesirable effects: Serious side effects: cellulitis, herpes zoster, serious hypersensitivity reactions, anaphylaxis, angioedema, organising pneumonia, eosinophilic pneumonia, exfoliative dermatitis, 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)

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

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

Date of preparation: April 2024

Unique ID number: UK-Uzpru-9

Adverse events should be reported. Reporting forms and information can be found at: www.mhra.gov.uk/yellowcard 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@midinformation.co.uk or by calling 01484 848164.

†Supply chain is constantly being optimised and manufacturing location is subject to change. ††Stelara.®

*Plunger stopper made of bromobutyl rubber. **29 vs 27-gauge needle of the reference product, Stelara.®

1. Uzpruvo SmPC. Available at [emc link when available]. Last accessed: June 2024.
2. Cost of Uzpruvo and reference product taken from NHS DM+D. Available at: https://dmdbrowser.nhsbsa.nhs.uk. Accessed [July] 2024.
3. 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-growthin-2022. Last accessed: June 2024.
4. Feldman SR et al. Expert Opin Biol Ther. 2023;23(3):253-60.
5. Stelara package insert. Available at: https://www.janssenlabels.com/package-insert/product-monograph/prescribinginformation/STELARA-pi.pdf. Accessed June 2024.
6. Jaber A et al. BMC Neurol. 2008;8:38.

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