Made for us

- **Indicated for Plaque Psoriasis, Paediatric Plaque Psoriasis, Psoriatic Arthritis, Crohn's Disease[1]**
- **The NEW ustekinumab biosimilar from Clonmel Healthcare[1]**
- **Uzpruvo is the first approved ustekinumab biosimilar in Ireland**

Cost-effective option enabling improved access to ustekinumab treatment

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

Patient-friendy PFS: easy handling, thinner needle†, latex-free††[1,3]

Uzpruvo® is currently not approved for the ulcerative colitis indication (since the originator still has exclusivity for this indication).

▼This medicinal product is subject to additional monitoring.

*Stelara®; † 29 vs 27-gauge needle of the reference product, Stelara®[1,3]

UZPRUVO® ▼
ustekinumab

SWITCHING FROM REFERENCE TO BIOSIMILAR[1]

A biosimilar is a biological medicine **highly similar** to another already approved biological medicine (the 'reference product'). **Interchangeability** in this context means that the reference medicine can be replaced by a biosimilar **that is expected to have the same clinical effect**

The EMA and the HMA have issued a joint statement confirming that **biosimilar medicines approved in the EU are interchangeable with their reference medicines**

The EMA has approved 81 biosimilar medicines since 2006. These medicines have been thoroughly reviewed and monitored over the past 15 years and the experience from clinical practice has shown that in terms of efficacy, safety and immunogenicity they are comparable to their reference products and are therefore interchangeable*[2,3]

Emer Cooke, EMA's Executive Director

EMA, European Medicines Agency; HMA, Heads of Medicines Agency

*As of January 2024 81 biosimilars have been approved[3]

1. 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 Jan. 2024; 2. European Medicines Agency. Biosimilar medicines can be interchanged. Available at: https://www.ema.europa.eu/en/news/biosimilar-medicines-can-be-interchanged. Last accessed Jan. 2024; 3. Übersicht über zentralisiert in der EU zugelassene Biosimilars. Available at: https://www.vfa.de/de/arzneimittel-forschung/datenbanken-zu-arzneimitteln/biosimilars-uebersicht. Last accessed Jan. 2024.

INTRODUCING UZPRUVO®:
THE NEW USTEKINUMAB BIOSIMILAR TO BE LAUNCHED IN IRELAND

Uzpruvo® is the first approved ustekinumab biosimilar in Ireland and offers a high quality, affordable alternative to the reference product*[1]

UZPRUVO® ustekinumab

An ustekinumab biosimilar with **similar efficacy, quality and safety profile** to the reference product*[1]

Unique mode of action of ustekinumab as an **IL-12/23 inhibitor**[2]

Made available by Clonmel Healthcare with a **European supply chain****[2]

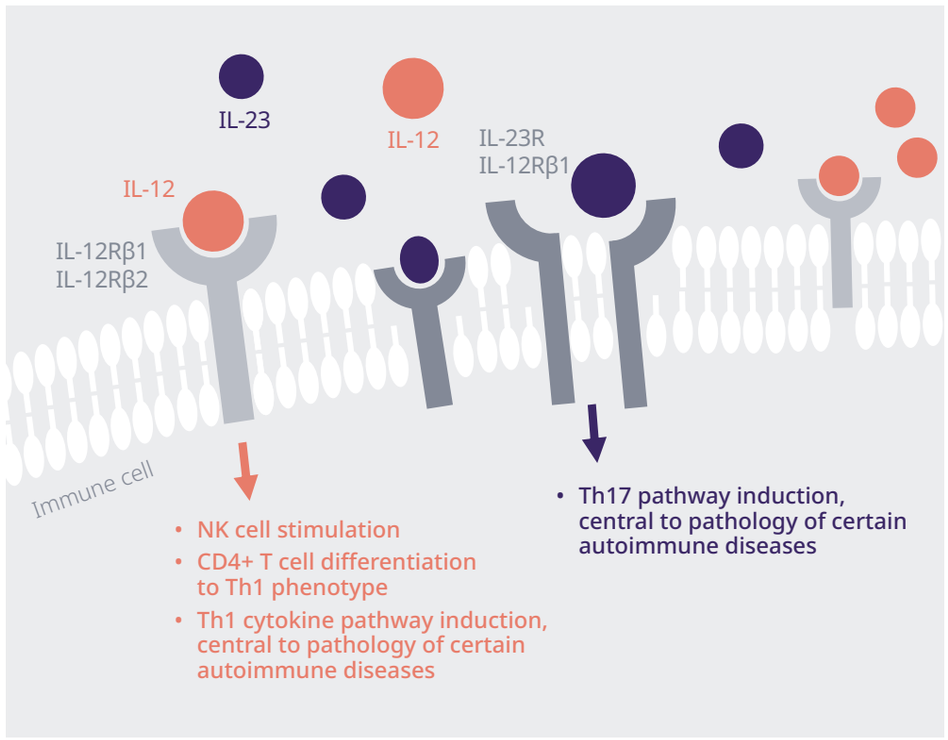
IL, interleukin

*Stelara® (ustekinumab); **Supply chain is constantly being optimised and manufacturing location is subject to change

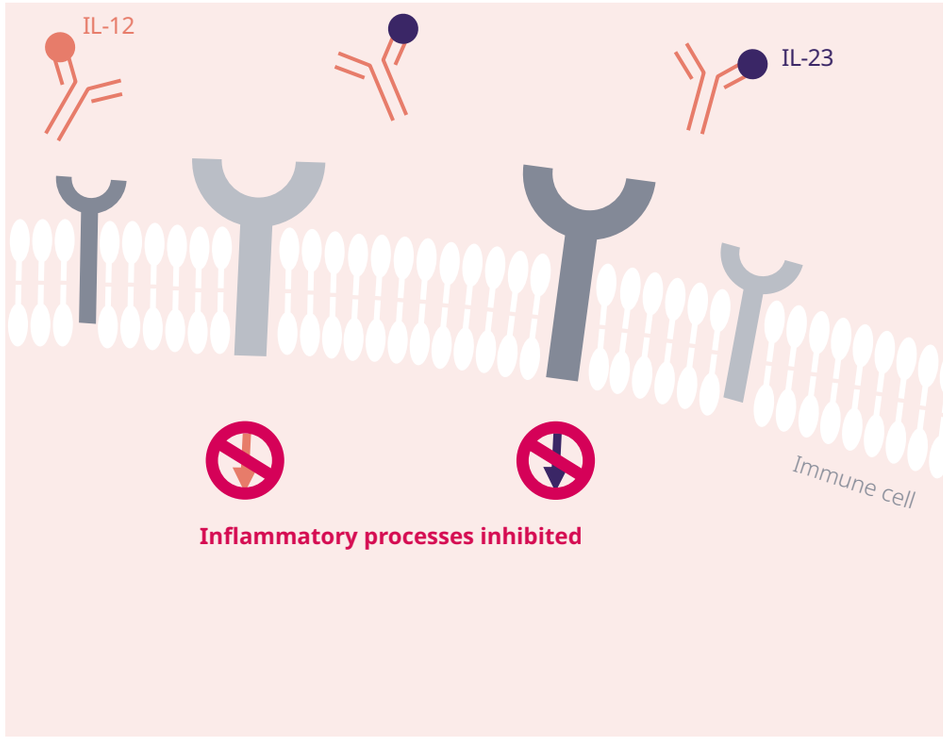
1. Uzpruvo® EPAR public assessment report (Feb. 2024); 2. Uzpruvo® SmPC (Feb. 2024).

UNIQUE MODE OF ACTION OF USTEKINUMAB: **IL12/IL23-RECEPTOR BINDING INHIBITION**

Autoimmune disease **without** Uzpruvo®



Autoimmune disease **with** Uzpruvo®



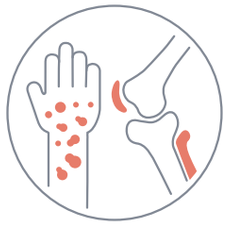
Ustekinumab is a fully human $IgG1_K$ monoclonal antibody that binds with specificity to the shared p40 protein subunit of pro-inflammatory cytokines **IL-12 and IL-23** to prevent them from binding to their receptors, expressed on the surface of immune cells, therefore inhibiting inflammatory processes early[1]

CD, cluster of differentiation; Ig, immunoglobulin; IL, interleukin; NK, natural killer; Th, T helper

1. Uzpruvo® SmPC (Feb. 2024).

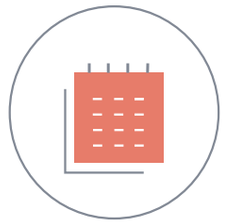
UZPRUVO® ustekinumab

UZPRUVO® FOR YOUR **DERMATOLOGY AND RHEUMATOLOGY PATIENTS**

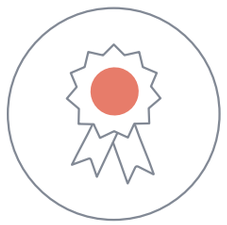


Indications

Convenient dosing scheme[1]



Dermatology and rheumatology treatment regimes



Ustekinumab in guidelines

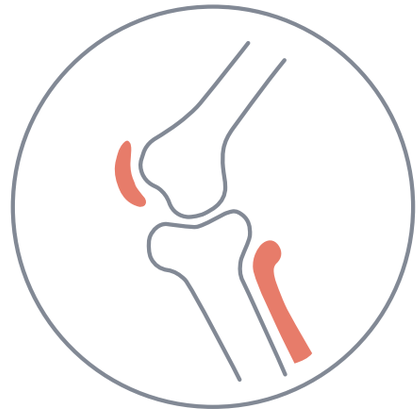
Efficacy of ustekinumab in dermatology and rheumatology

1. Uzpruvo® SmPC (Feb. 2024).

INDICATIONS IN DERMATOLOGY AND RHEUMATOLOGY[1]

Within dermatology and rheumatology, Uzpruvo® is approved to treat:

PLAQUE PSORIASIS AND PAEDIATRIC PLAQUE PSORIASIS



PSORIATIC ARTHRITIS

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

1. Uzpruvo® SmPC (Feb. 2024).

UZPRUVO® ustekinumab

UZPRUVO® IN DERMATOLOGY & RHEUMATOLOGY: **POSOLOGY OPTIONS**[1]

Choose between two dose strengths to suit individual treatment needs

Induction and maintenance: SC injection

Presentation:
Pre-filled syringe

Dose	45 mg/ 0.5 mL	90 mg/ mL

SC, subcutaneous

1. Uzpruvo® SmPC (Feb. 2024).

UZPRUVO® ustekinumab

CONVENIENT DOSING SCHEME[1]

Uzpruvo® offers individual convenient dosing options for the specific dermatology indications

	Indication	Induction dose	Maintenance dose
	**Plaque psoriasis**	SC injection via PFS in Week 0 and 4: BW ≤100 kg: 45 mg BW >100 kg: 90 mg	Q12W: Same as induction dose
	**Paediatric plaque psoriasis (≥6 years old)**	SC injection via PFS in Week 0 and 4: BW ≥60 to ≤100 kg: 45 mg BW >100 kg: 90 mg	Q12W: Same as induction dose
	**Psoriatic arthritis**	SC injection via PFS in Week 0 and 4: BW ≤100 kg: 45 mg BW >100 kg: 90 mg	Q12W: Same as induction dose

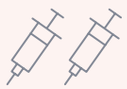
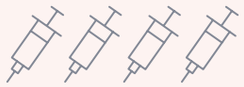
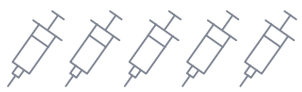
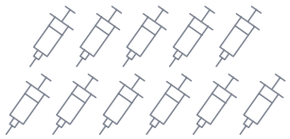
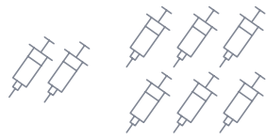
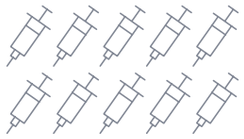
BW, body weight; PFS, pre-filled syringe; Q12W, every 12 weeks; SC, subcutaneous

1. Uzpruvo® SmPC (Feb. 2024).

UZPRUVO® ustekinumab

COMPARATIVELY FEWER TREATMENTS: **DERMATOLOGY & RHEUMATOLOGY TREATMENT REGIMES**[1–3]

Example of total doses in the first year of treatment (52 weeks) for adult patients with plaque psoriasis

Uzpruvo® (ustekinumab)[1]	**6** doses	**Induction** 	**Maintenance** 	2 weight-based (45 or 90 mg) SC induction dose injections in W 0 and 4; 4 weight-based maintenance dose injections (one Q12W after induction dose)*
Secukinumab[2]	**16** doses	**Induction** 	**Maintenance** 	5 induction dose injections of 300 mg in W 0–4; 11 SC maintenance dose injections of 300 mg (one Q4W)**
Ixekizumab[3]	**18** doses	**Induction** 	**Maintenance** 	2 induction dose injections in W 0 (160 mg given as 2 x 80 mg injections), followed by 6 SC injections Q2W until W 12 of 80 mg; 10 maintenance SC injections of 80 mg

 Injection

Q2W, every 2 weeks; Q4W, every 4 weeks; Q12W, every 12 weeks; SC, subcutaneous; W, week(s)

*Uzpruvo® weight-based dosage regime: BW ≤100 kg: 45 mg, BW >100 kg: 90 mg; **Numbers based on the use of a 300 mg dosage. Secukinumab weight-based dosage frequency is Q4W for patient with BW <90 kg and Q2W with BW ≥90 kg[2]

1. Uzpruvo® SmPC (Feb. 2024); 2. Cosentyx® SmPC (Aug. 2023); 3. Taltz® SmPC (Feb. 2023).

UZPRUVO® ustekinumab

EDF GUIDELINES RECOMMEND USTEKINUMAB*[1] FOR PLAQUE PSORIASIS

Plaque psoriasis

Ustekinumab is recommended for patients who have an inadequate response to, are contraindicated to, or cannot tolerate conventional therapy[1]

Adapted from Nast A et al. 2020[1]

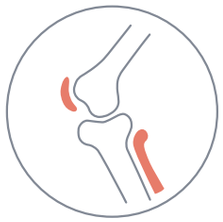
EDF, European Dermatolgy Forum; IL, interleukin; PDE4, phosphodiesterase 4; TNF, tumour necrosis factor

*These abbreviated guidelines provide an overview of strong recommendations but do not contain details presented in full recommendations

1. Nast A et al. J Eur Acad Dermatol Venereol. 2020;34:2461-98.

UZPRUVO® ustekinumab

EULAR RECOMMENDS USTEKINUMAB*[1]
FOR PSORIATIC ARTHRITIS



Psoriatic arthritis

Ustekinumab is recommended for patients who have an inadequate response to conventional therapy[1]

Inadequate response to conventional therapy → **Start bDMARD: anti-TNF or anti-IL12/23 (ustekinumab) or anti-IL17**

bDMARD, biological DMARD; DMARD, disease-modifying anti-rheumatic drug; EULAR, European Alliance of Associations for Rheumatology; IL, interleukin; TNF, tumour necrosis factor

*These abbreviated guidelines provide an overview of strong recommendations but do not contain details presented in full recommendations

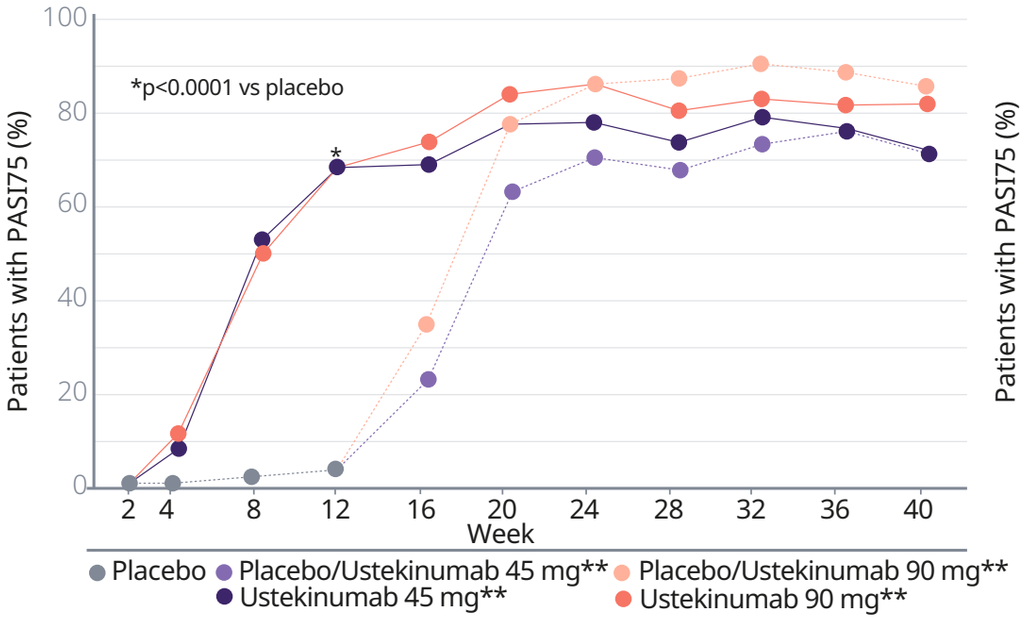
1. Gossec L et al. Ann Rheum Dis. 2020;79(6):700-12.

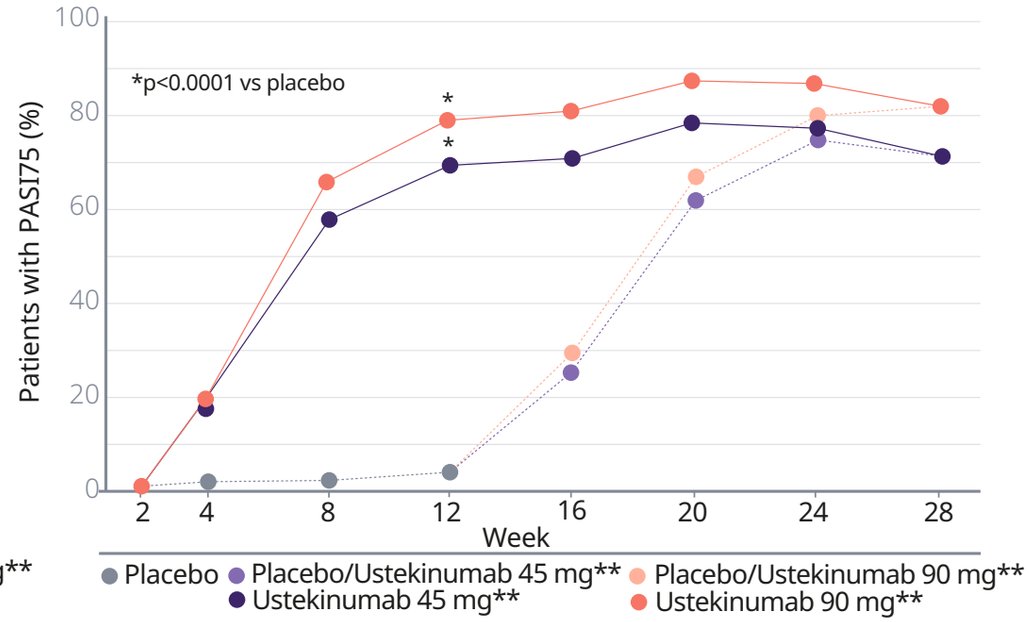
UZPRUVO® ustekinumab

EFFICACY OF USTEKINUMAB VS PLACEBO: **SIGNIFICANT IMPROVEMENT IN PASI***[1,2]

Primary endpoint: **Significantly higher PASI75 rates at Week 12** in both ustekinumab treatment groups vs placebo[1,2]

PHOENIX1 and PHOENIX2





Furthermore **long-term response** had been **achieved through Week 40**[1]

Adapted from Leonardi C et al. 2008[1] and Papp KA et al. 2008[2]

PASI, Psoriasis Activity Severity Index

*Shown in studies with the reference product, Stelara®; **The recommended dose in adult psoriasis patients is 45 mg ≤100kg or 90 mg >100 kg (45 mg was also shown to be efficacious, however, 90 mg resulted in greater efficacy)[3]

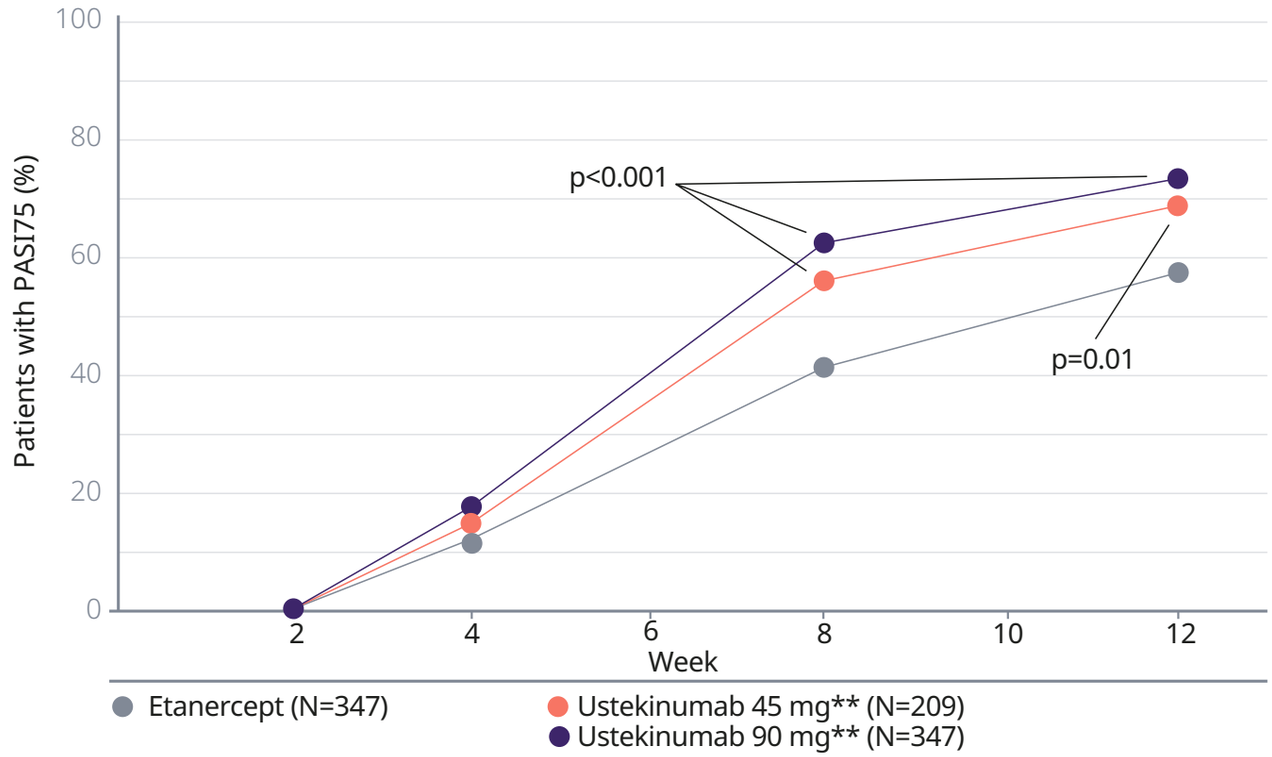
1. Leonardi C et al. Lancet. 2008;371(9625):1665-74; 2. Papp KA et al. Lancet. 2008;371(9625):1675-84; 3. Stelara® SmPC (Dec. 2023).

UZPRUVO® ustekinumab

EFFICACY OF USTEKINUMAB VS ETANERCEPT: **SIGNIFICANTLY HIGHER PASI75 RATE***[1]

Primary endpoint: **Significantly higher PASI75 rate at Week 12** in both ustekinumab treatment groups **vs etanercept**

ACCEPT



Adapted from Griffiths CEM et al. 2010[1]

PASI, Psoriasis Activity Severity Index

*Shown in a study with the reference product, Stelara®; **The recommended dose in adult psoriasis patients is 45 mg ≤100 kg or 90 mg >100 kg (45 mg was also shown to be efficacious, however, 90 mg resulted in greater efficacy)[2]

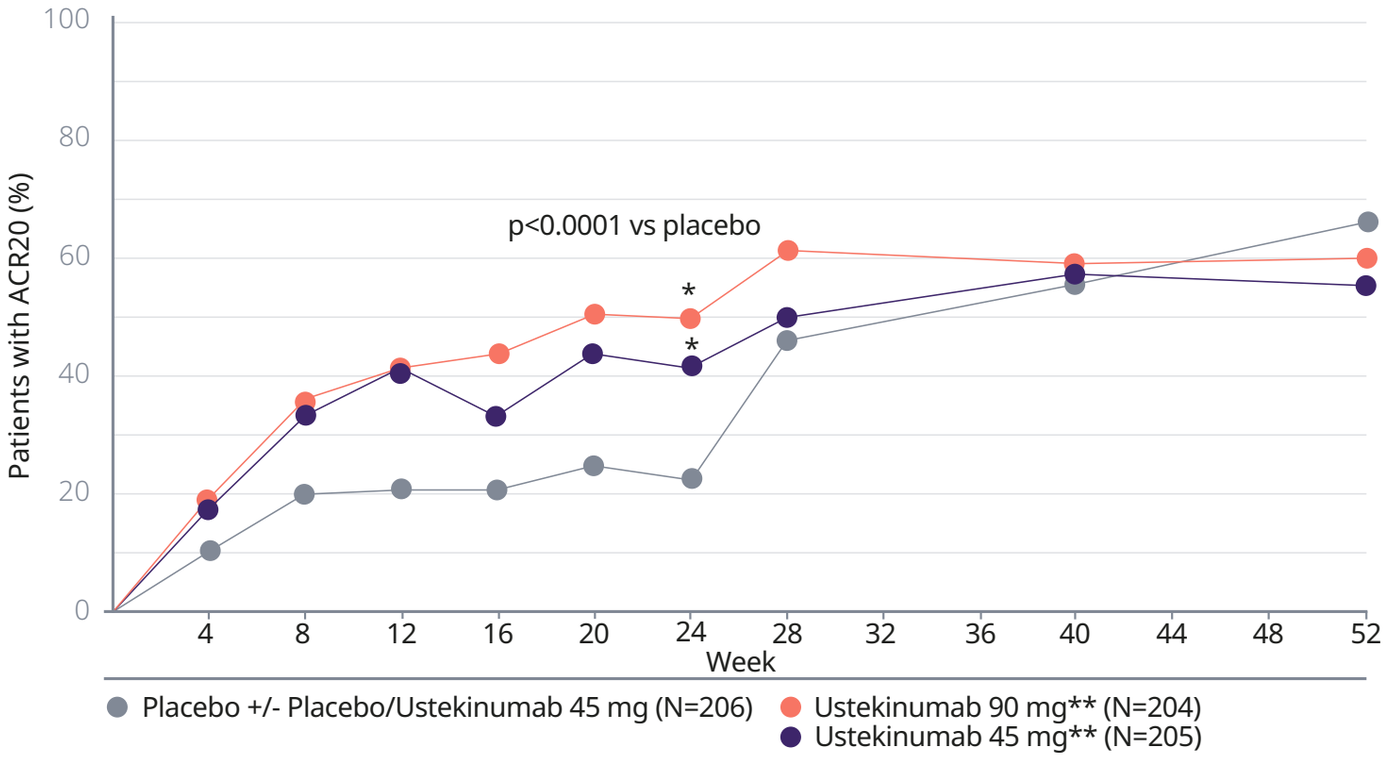
1. Griffiths CEM et al. N Engl J Med. 2010;362(2):118-28; 2. Stelara® SmPC (Dec. 2023).

UZPRUVO® ustekinumab

EFFICACY OF USTEKINUMAB VS PLACEBO: **SIGNIFICANTLY HIGHER ACR20 RATE***[1]

Primary endpoint: **Significantly higher ACR20 rate at Week 24** in both ustekinumab treatment groups vs placebo

PSUMMIT-I[1]



Adapted from McInnes IB et al. 2013[1]

ACR, American College of Rheumatology

*Shown in a study with the reference product, Stelara®; **The recommended dose in adult psoriasis patients is 45 mg ≤100 kg or 90 mg >100 kg (45 mg was also shown to be efficacious, however, 90 mg resulted in greater efficacy)[2]

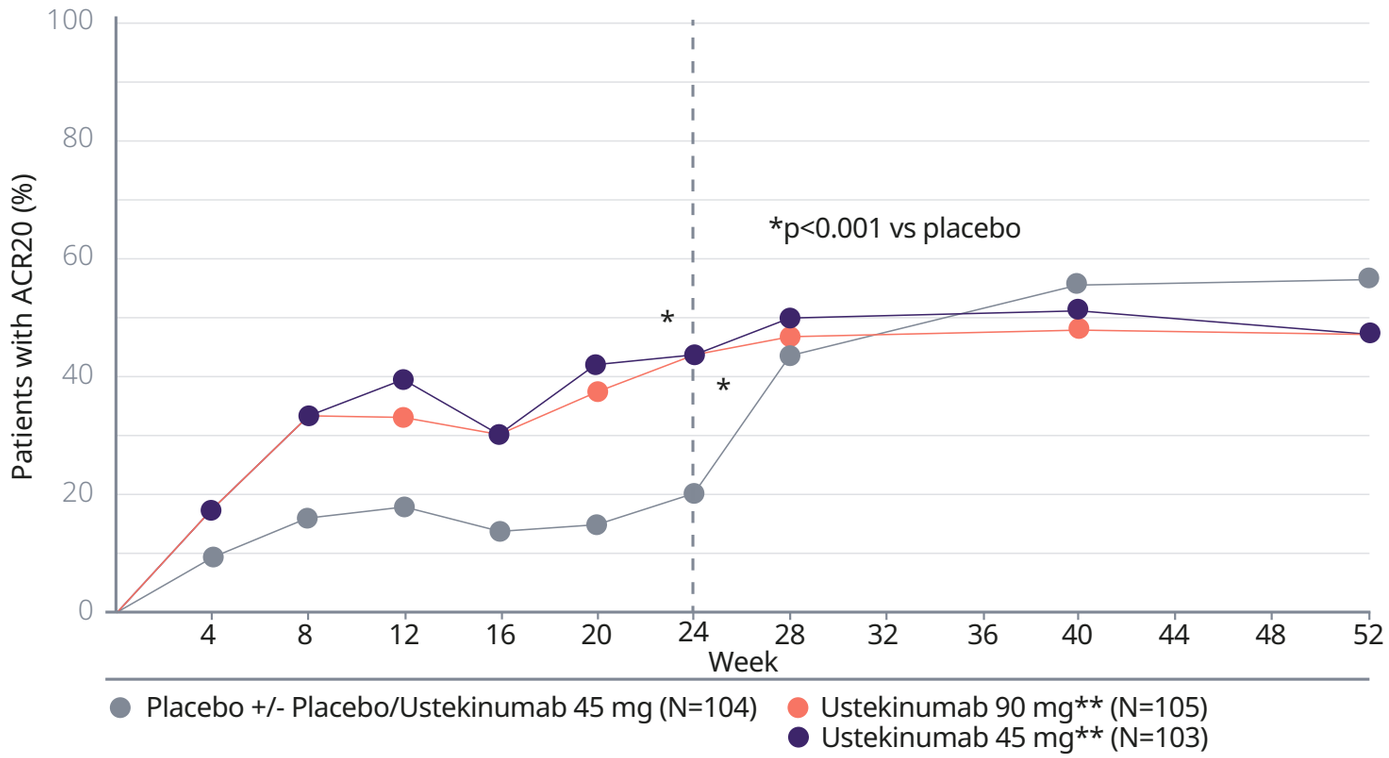
1. McInnes IB et al. Lancet. 2013;382(9894):780-89; 2. Stelara® SmPC (Dec. 2023).

UZPRUVO® ustekinumab

EFFICACY OF USTEKINUMAB VS PLACEBO: **SIGNIFICANTLY HIGHER ACR20 RATE***[1]

Primary endpoint: **Significantly higher ACR20 rate at Week 24** in both ustekinumab treatment groups vs placebo

PSUMMIT-II[1]



Adapted from Ritchlin C et al. 2014[1]

ACR, American College of Rheumatology

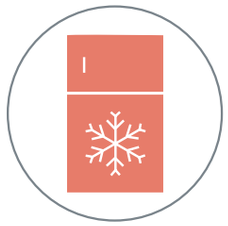
*Shown in a study with the reference product, Stelara®; **The recommended dose in adult psoriasis patients is 45 mg ≤100 kg or 90 mg >100 kg (45 mg was also shown to be efficacious, however, 90 mg resulted in greater efficacy)[2]

1. Ritchlin C et al. Ann Rheum Dis. 2014;73(6):990-92; 2. Stelara® SmPC (Dec. 2023).

UZPRUVO® ustekinumab

AT A GLANCE:
UZPRUVO® FEATURES

Easy-to-handle, patient-friendly syringe



Convenient storage options[1]

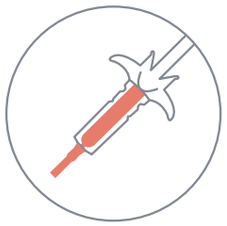
Homecare Support

1. Uzpruvo® SmPC (Feb. 2024).

UZPRUVO® ustekinumab

DIFFERENT DOSE STRENGTHS
FOR INDIVIDUAL NEEDS[1]

Choose between dose strengths to suit individual treatment needs



45 mg/0.5 mL

Pack of 1

90 mg/mL

Pack of 1

1. Uzpruvo® SmPC (Feb. 2024).

UZPRUVO®
ustekinumab

PRE-FILLED SYRINGE:
DESIGNED WITH PATIENTS' COMFORT IN MIND

The Uzpruvo® pre-filled syringe has been designed specifically for easy handling and a patient-friendly injection experience, allowing for a seamless transition

Extended finger flange

Needlestick injury prevention: needle springs back into the protective cover after injection[1]

Latex free*: patients with latex allergies can use Uzpruvo® with confidence[1]

Thinner needle (29-gauge)** for reduced pain on injection[1–3]

45 mg/0.5 mL
and
90 mg/mL

*Plunger stopper made of bromobutyl rubber[1]; **Vs the administration device of the reference product, Stelara®, which has a wider 27-gauge needle[2]

1. Uzpruvo® SmPC (Feb. 2024); 2. Stelara® PI (Aug. 2022); 3. Jaber A et al. BMC Neurol. 2008;8:38.

UZPRUVO® ustekinumab

SIMPLE STORAGE AND SHELF-LIFE

Uzpruvo® storage requirements are simple[1]

45 mg or 90 mg
pre-filled syringe

Refrigeration storage (2–8°C) Shelf-life	2 years
Room temperature (max. 30°C) Shelf-life	30 days

Uzpruvo® should be stored in a refrigerator at 2–8°C and must not be frozen

Uzpruvo® should be stored in its outer carton before use to protect it from light

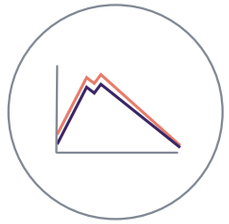
When needed, Uzpruvo® pre-filled syringes can be stored at room temperature (max. 30°C) for up to 30 days, by which point they must be used or discarded

max, maximum

1. Uzpruvo® SmPC (Feb. 2024).

UZPRUVO® ustekinumab

UZPRUVO® VS THE REFERENCE PRODUCT*: **CLONMEL HEALTHCARE'S PROVEN USTEKINUMAB BIOSIMILAR**[1]



Similar PK profile[2]

Similar efficacy**[3]

Similar safety profile**[3]

Similar immunogenicity profile**[3]

Phase III trial design

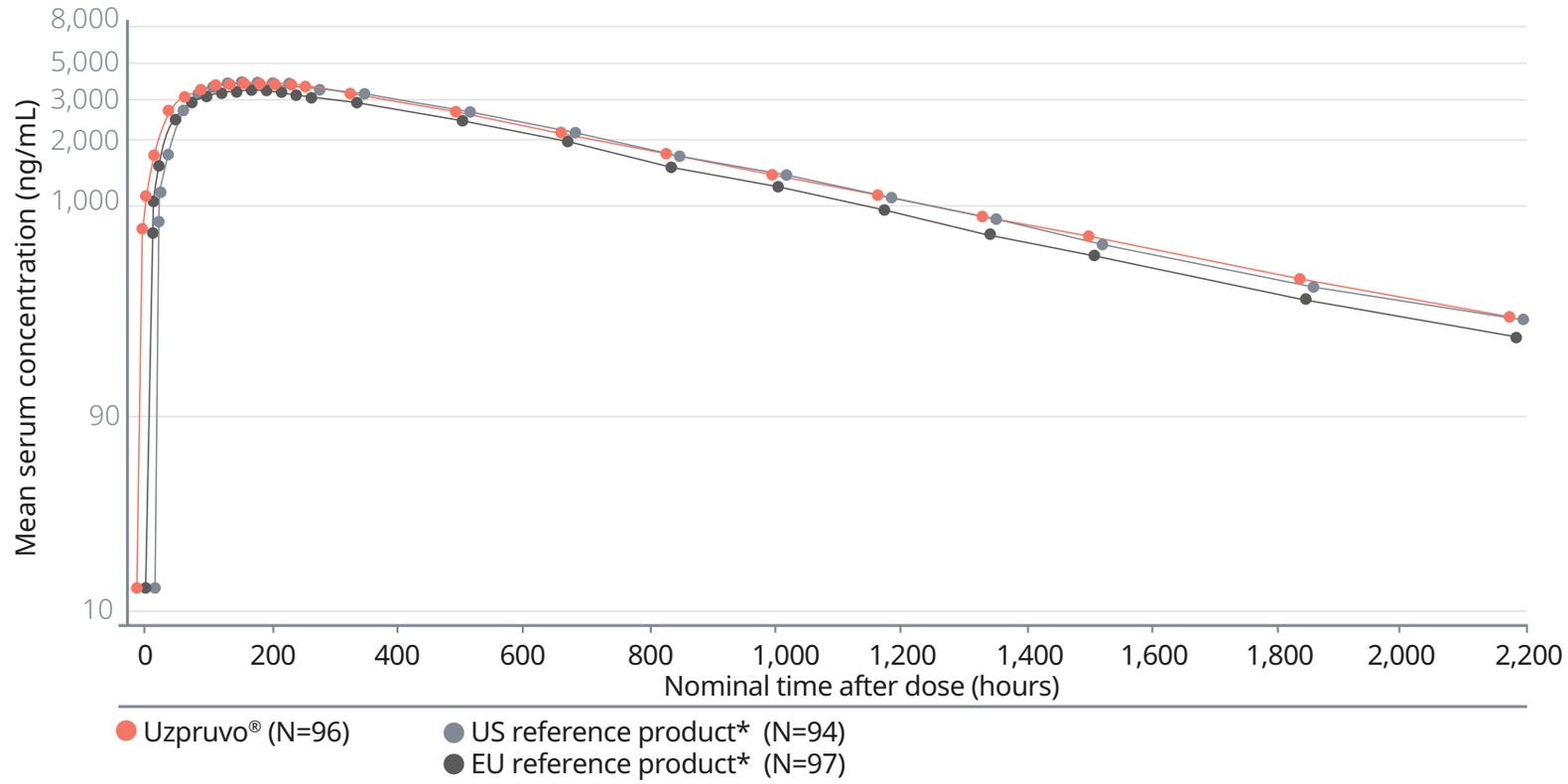
*Stelara®; **Demonstrated in a Phase III clinical study of patients with moderate-to-severe chronic plaque psoriasis[3]

1. Uzpruvo® EPAR public assessment report (Feb. 2024); 2. Wynne C et al. Expert Opin Investig Drugs. 2023;32(5):417-27; 3. Feldman SR et al. Expert Opin Biol Ther. 2023;23(3):253-60. DOI: 10.1080/14712598.2023.2235263.

UZPRUVO® VS THE REFERENCE PRODUCT*: **SIMILAR PK PROFILE[1]**

Similar mean serum ustekinumab concentration-time profiles for Uzpruvo® and the reference products*

Primary endpoint: Mean (± SD) serum concentration-time profile of ustekinumab by treatment group (PK population)



Adapted from Wynne C et al. 2023[1]

BLQ, below the limit of quantification; LLOQ, lower limit of quantitation; PK pharmacokinetic; SD, standard deviation

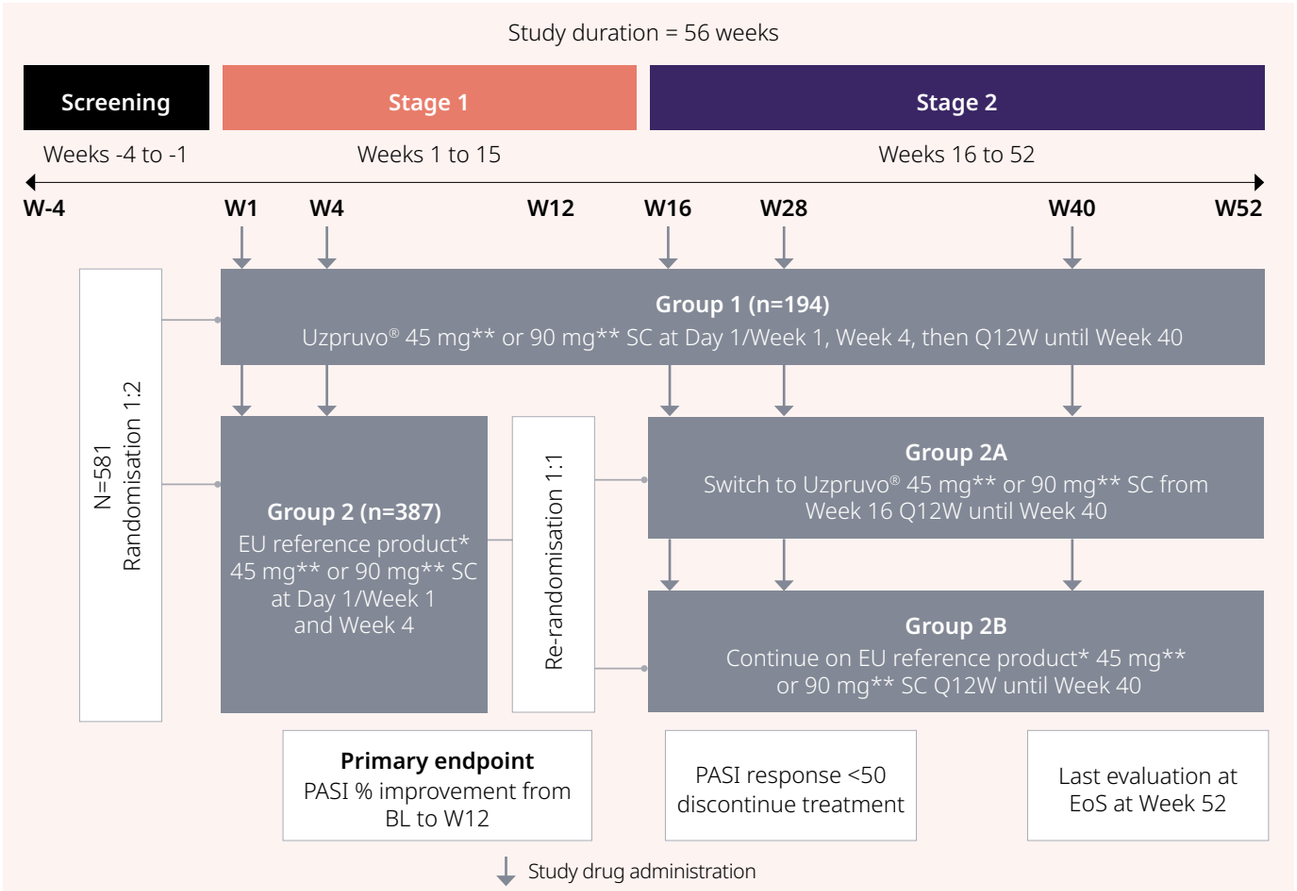
All predose BLQ values were substituted by zeros. Thereafter, BLQ values between evaluable concentrations and terminal BLQ were set to 0.5 x LLOQ

*EU-approved Stelara® and US-approved Stelara®

1. Wynne C et al. Expert Opin Investig Drugs. 2023;32(5):417-27.

UZPRUVO® ustekinumab

UZPRUVO® VS THE REFERENCE PRODUCT*:
PHASE III TRIAL DESIGN[1]



Primary objective:

PASI % improvement from BL to Week 12

Secondary objective

- ✓ PASI 50/75/90/100 response rates from BL at Weeks 4, 8, 12, 16, 28, 40 and 52
- ✓ PASI % improvement from BL to Weeks 4, 8, 16, 28, 40 and 52
- ✓ sPGA responses
- ✓ Change from baseline in DLQI and BSA affected by psoriasis
- ✓ Additional secondary assessments were safety, serum trough concentrations at steady state and immunogenicity

Adapted from Feldman SR et al. 2023[1]

BL, baseline; BSA, body surface area; DLQI, Dermatology life quality index; EoS, end of study; PASI, Psoriasis Area and Severity Index; Q12W, every 12 weeks; SC, subcutaneous; sPGA, statistic physician's global assessment
*Stelara®; **≤100 kg body weight: 45 mg, >100 kg body weight: 90 mg

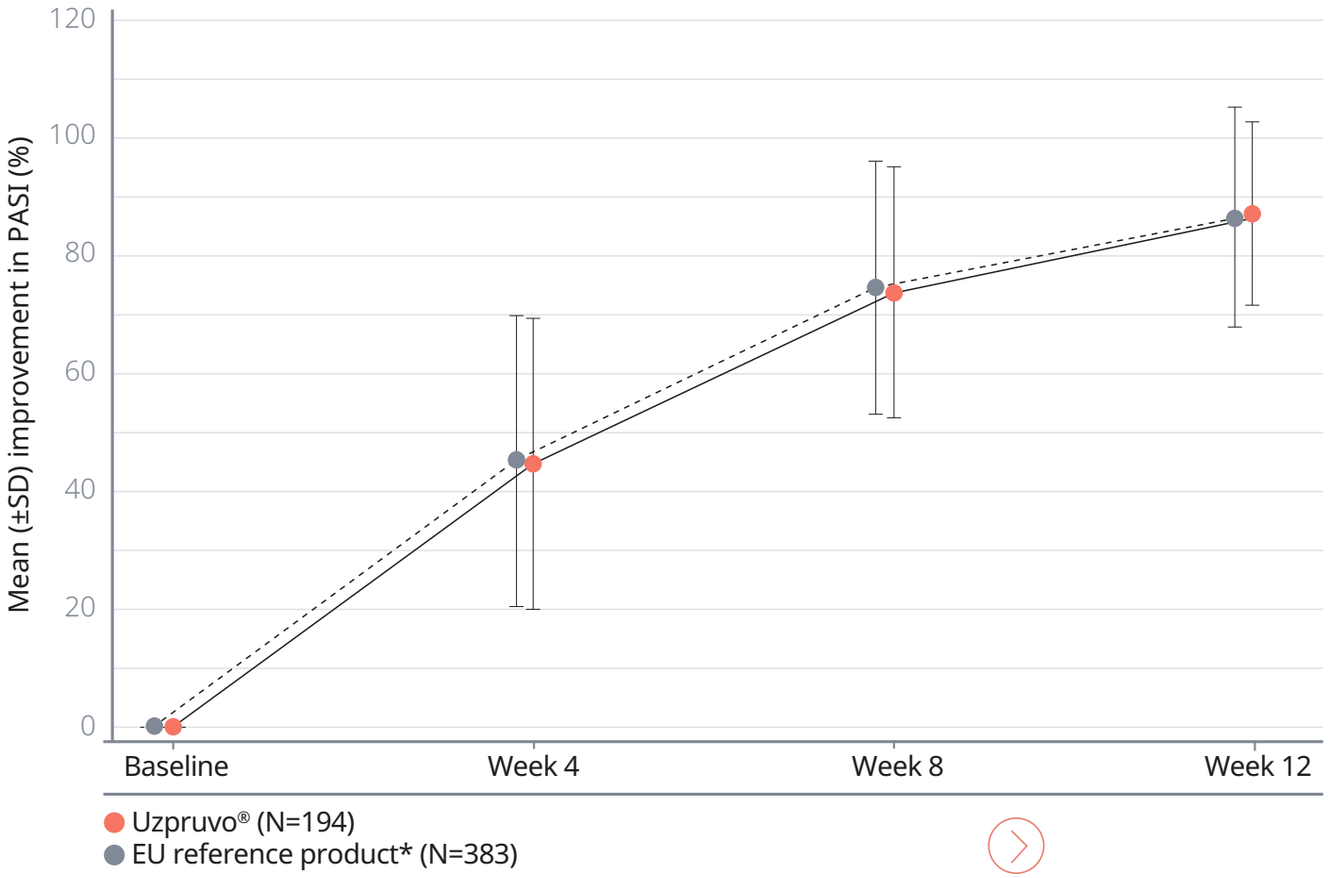
1. Feldman SR et al. Expert Opin Biol Ther. 2023;23(3):253-60. DOI: 10.1080/14712598.2023.2235263.

UZPRUVO® ustekinumab

UZPRUVO® VS THE REFERENCE PRODUCT*: **SIMILAR EFFICACY**[1]

The study primary endpoint was met: the percent **improvement in PASI** from BL to Week 12 for Uzpruvo® (87.3%) and the reference product* (86.8%) **was similar****

Primary endpoint: Improvement in PASI from BL up to Week 12



Adapted from Feldman SR et al. 2023[1]

ANCOVA, analysis of covariance; BL, baseline; CI, confidence interval; PASI, Psoriasis Area and Severity Index; SD, standard deviation

ANCOVA analysis. The 90% CI (-2.14, 3.01) and 95% CI (□2.63, 3.50) for the primary endpoint were within the equivalence margins (±10%/±15%)

*Stelara®; **In patients with body weight ≤100 kg, similar PASI improvement was observed in both treatment arms (Uzpruvo® 86.9% vs EU reference product 86.8%); the 95% CI for the LS means difference (0.1) in percent PASI improvement from baseline to Week 12 was □3.25%, 3.43%, within the predefined EMA equivalence margin of ±15%

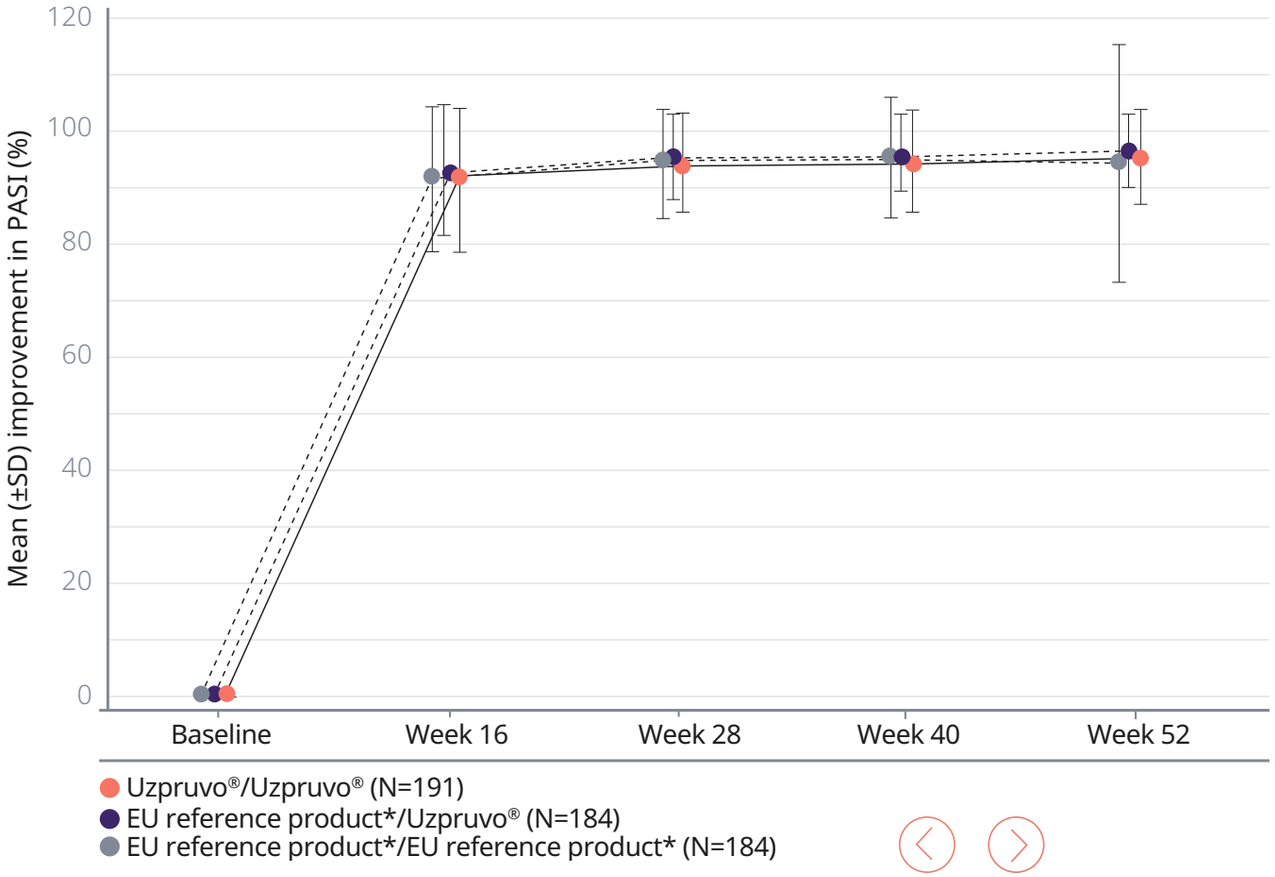
1. Feldman SR et al. Expert Opin Biol Ther. 2023;23(3):253-60. DOI: 10.1080/14712598.2023.2235263.

UZPRUVO® ustekinumab

UZPRUVO® VS THE REFERENCE PRODUCT*: **SIMILAR EFFICACY**[1]

Similar long-term efficacy, even after switching: the percent **improvement in PASI** from BL to Week 52 for Uzpruvo® and the reference product* **was comparable**

Secondary endpoint: Improvement in PASI from BL up to Week 52



Adapted from Feldman SR et al. 2023[1]

BL, baseline; PASI, Psoriasis Area and Severity Index; SD, standard deviation

*Stelara®

1. Feldman SR et al. Expert Opin Biol Ther. 2023;23(3):253-60. DOI: 10.1080/14712598.2023.2235263.

UZPRUVO® ustekinumab

UZPRUVO® VS THE REFERENCE PRODUCT*: **SIMILAR EFFICACY, EVEN AFTER SWITCHING**[1]

Switching treatment from the reference product* to Uzpruvo® did not result in any clinically meaningful differences in secondary efficacy endpoints

Across the switched and continued treatment groups, there was no clinically meaningful difference in…

Percent improvement in PASI

sPGA responses

DLQI improvement

Percentage BSA affected by chronic PsO

BSA, body surface area; DLQI, dermatology life quality index; PASI, Psoriasis Area and Severity Index; PsO, plaque psoriasis; sPGA, static Physician Global Assessment

*Stelara®

1. Feldman SR et al. Expert Opin Biol Ther. 2023;23(3):253-60. DOI: 10.1080/14712598.2023.2235263.

UZPRUVO® ustekinumab

UZPRUVO® VS THE REFERENCE PRODUCT*:
SIMILAR SAFETY PROFILE, EVEN AFTER SWITCHING[1]

Comparable AE profiles for Uzpruvo® and the reference product* up to Week 52, even after switching

Secondary endpoint: Overview of TEAEs per therapeutic indication (safety analysis set)

	Up to Week 16		Weeks 16 to 28			Weeks 28 to 52		
System organ class preferred term	Uzpruvo®	EU RP*	Uzpruvo®/ Uzpruvo®	EU RP*/ Uzpruvo®	EU RP*/ EU RP*	Uzpruvo®/ Uzpruvo®	EU RP*/ Uzpruvo®	EU RP*/ EU RP*
Patients n (%)	(N=194)	(N=387)	(N=193)	(N=192)	(N=189)	(N=191)	(N=184)	(N=184)
Any TEAE	67 (34.5)	130 (33.6)	21 (10.9)	30 (15.6)	29 (15.3)	32 (16.8)	42 (22.8)	39 (21.2)
Treatment-related TEAEs	10 (5.2)	37 (9.6)	0	5 (2.6)	2 (1.1)	0	3 (1.6)	6 (3.3)
Serious TEAEs	0	7 (1.8)	0	0	1 (0.5)	1 (0.5)	1 (0.5)	1 (0.5)
Serious TEAEs (treatment-related)	0	0	0	0	0	0	0	0
TEAE leading to discontinuation	0	3 (0.8)	1 (0.5)	3 (1.6)	4 (2.1)	0	0	1 (0.5)
TEAE leading to discontinuation (treatment-related)	0	0	0	0	0	0	0	0
Death	0	0	0	0	0	0	0	0
Injection site reation	2 (1.0)	9 (2.3)	0	1 (0.5)	1 (0.5)	0	1 (0.5)	2 (1.1)
Skin and subcutaneous tissue disorder	0	2 (0.5)	0	0	0	0	0	0
Infections and infestations	0	0	0	0	0	0	1 (0.5)	0
Lower respiratory tract infection	0	0	0	0	0	0	1 (0.5)	0

Adapted from Feldman SR et al. 2023[1]

AE, adverse event; RP, reference product; TEAE, treatment-emergent adverse event

*Stelara®

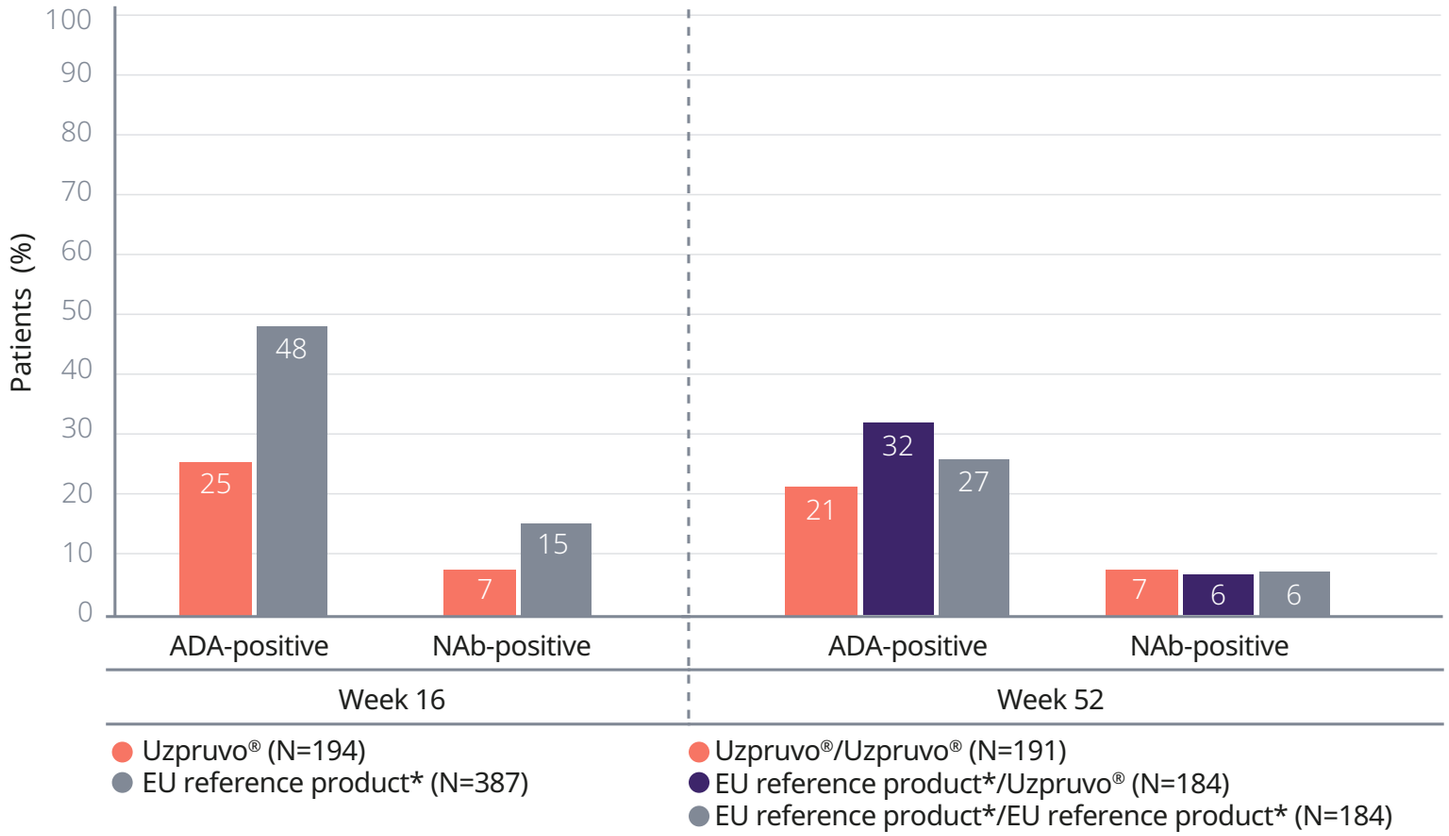
1. Feldman SR et al. Expert Opin Biol Ther. 2023;23(3):253-60. DOI: 10.1080/14712598.2023.2235263.

UZPRUVO® ustekinumab

UZPRUVO® VS THE REFERENCE PRODUCT*: **SIMILAR IMMUNOGENICITY, EVEN AFTER SWITCHING**[1]

The incidence of treatment emergent ADAs up to Week 52 **did not have any clinically meaningful difference** for Uzpruvo® and the reference product*, even after switching. NAb frequencies remained **consistent over time**

Confirmed positive ADA- and Nab incidence by visits (safety analysis set)



Adapted from Feldman SR et al. 2023[1]

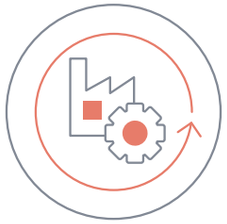
ADA, anti-drug antibodies; NAbs, neutralising antibodies

*Stelara®

1. Feldman SR et al. Expert Opin Biol Ther. 2023;23(3):253-60. DOI: 10.1080/14712598.2023.2235263.

UZPRUVO® ustekinumab

WHY CHOOSE UZPRUVO®?[1]



European manufacturing[1] and supply chain*

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

Nurse Support Program

Patient-friendly PFS: easy handling, thinner needle†, latex-free††[1,3]

Cost-effective option enabling improved access to ustekinumab treatment

PFS, pre-filled syringe

*Supply chain is constantly being optimised and manufacturing location is subject to change; **Stelara®; †29 vs 27-gauge needle of the reference product, Stelara®[3]; ††Plunger stopper made of bromobutyl rubber

1. Uzpruvo® SmPC (Feb. 2024); 2. Feldman SR et al. Expert Opin Biol Ther. 2023;23(3):253-60. DOI: 10.1080/14712598.2023.2235263; 3. Stelara® PI (Aug. 2022).

UZPRUVO 45 & 90 mg SOLUTION FOR INJECTION IN PRE-FILLED SYRINGE

Uzpruvo 45 mg: Each pre-filled syringe contains 45 mg ustekinumab in 0.5 mL. **Uzpruvo 90 mg:** Each pre-filled syringe contains 90 mg ustekinumab in 1 mL. Ustekinumab is a fully human IgG1κ monoclonal antibody to interleukin (IL)-12/23 produced in a murine myeloma cell line using recombinant DNA technology. **Presentation:** Pre-filled glass syringe. **Indications:** Uzpruvo is indicated for the treatment of plaque psoriasis, paediatric plaque psoriasis, psoriatic arthritis (PsA) and Crohn's disease. **Dosage:** Uzpruvo is intended for use under the guidance and supervision of physicians experienced in the diagnosis and treatment of conditions for which Uzpruvo is indicated. Refer to Summary of Product Characteristics. **Method of administration:** Subcutaneous injection. **Contraindications:** Hypersensitivity to the active substance or to any of the excipients listed in section 6.1. Clinically important, active infection. **Warnings and precautions:** In order to improve the traceability of biological medicinal products, the name and batch number of the administered product should be clearly recorded. Ustekinumab may have the potential to increase the risk of infections and reactivate latent infections. Patients should be instructed to seek medical advice if signs or symptoms suggestive of an infection occur. If a patient develops a serious infection, the patient should be closely monitored and Uzpruvo should not be administered until the infection resolves. Immunosuppressants like ustekinumab have the potential to increase the risk of malignancy. Serious hypersensitivity reactions have been reported in the postmarketing setting, in some cases several days after treatment. Cases of allergic alveolitis, eosinophilic pneumonia, and non-infectious organising pneumonia have been reported during post-approval use of ustekinumab. Risk factors for cardiovascular disease should be regularly assessed during treatment with ustekinumab. It is recommended that live viral or live bacterial vaccines (such as Bacillus of Calmette and Guérin (BCG)) should not be given concurrently with Uzpruvo. Caution should be exercised when considering concomitant use of other immunosuppressants and Uzpruvo or when transitioning from other immunosuppressive biologics. It is not known whether ustekinumab may affect allergy immunotherapy. In patients with psoriasis, exfoliative dermatitis has been reported following ustekinumab treatment. Cases of lupus-related conditions have been reported in patients treated with Ustekinumab. Because there is a higher incidence of infections in the elderly population in general, caution should be used in treating the elderly. **Interactions:** Live vaccines should not be given concurrently with Uzpruvo. In psoriasis studies, the safety and efficacy of ustekinumab in combination with immunosuppressants, including biologics, or phototherapy have not been evaluated. In psoriatic arthritis studies, concomitant MTX use did not appear to influence the safety or efficacy of ustekinumab. In Crohn's disease and ulcerative colitis studies, concomitant use of immunosuppressants or corticosteroids did not appear to influence the safety or efficacy of Ustekinumab. **Fertility, pregnancy and lactation:** Women of childbearing potential should use effective methods of contraception during treatment and for at least 15 weeks after treatment. There are no adequate data from the use of ustekinumab in pregnant women. Animal studies do not indicate direct or indirect harmful effects with respect to pregnancy, embryonic/foetal development, parturition or postnatal development. As a precautionary measure, it is preferable to avoid the use of Uzpruvo in pregnancy. Limited data from published literature suggests that ustekinumab is excreted in human breast milk in very small amounts. Because of the potential for adverse reactions in nursing infants from ustekinumab, a decision on whether to discontinue breast-feeding during treatment and up to 15 weeks after treatment or to discontinue therapy with Uzpruvo must be made taking into account the benefit of breast-feeding to the child and the benefit of Uzpruvo therapy to the woman. The effect of ustekinumab on human fertility has not been evaluated. **Driving and operation of machinery:** Uzpruvo has no or negligible influence on the ability to drive and use machines. **Undesirable effects:** Upper respiratory tract infection, nasopharyngitis, sinusitis, dizziness, headache, oropharyngeal pain, diarrhoea, nausea, vomiting, pruritus, back pain, myalgia, arthralgia, fatigue, injection site erythema, injection site pain. Refer to Summary of Product Characteristics for other adverse effects. Adverse reactions should be reported via HPRA Pharmacovigilance, website: www.hpra.ie. **Pack size:** 1 pre-filled syringe. A copy of the Summary of Product Characteristics is available upon request or go to www.clonmelhealthcare.ie. **Marketing authorisation holder:** STADA Arzneimittel AG, Stadastrasse 2-18, 61118 Bad Vilbel, Germany. **Marketing authorisation number:** EU/1/23/1784/001,004. Medicinal product subject to restricted medical prescription. **Date last revised:** February 2024.

Date prepared: October 2024. 2024/ADV/UZP/256H

UZPRUVO® ustekinumab