Best-Value Biological Medicine (Ustekinumab): Pyzchiva®

Information for Healthcare Professionals

The MMP recommends Pyzchiva® as a Best-Value Biological (BVB) Medicine for ustekinumab.

Prescribing Pyzchiva® reduces the financial burden on the HSE arising out of the funding of reimbursed medicines, and can assist in facilitating access to new, innovative medicines for patients.

The following presentations of Pyzchiva®▼[a,b] are recommended as best-value biological (BVB) medicines:

- Pyzchiva® 45 milligrams (mg) solution for injection in pre-filled pen
- Pyzchiva® 90 mg solution for injection in pre-filled pen
- Pyzchiva® 45 mg solution for injection in pre-filled syringe
- Pyzchiva® 90 mg solution for injection in pre-filled syringe
- Pyzchiva® 130 mg concentrate for solution for infusion vial.

Pyzchiva® is licensed for the treatment of:[b]

- plaque psoriasis in adults
- paediatric plaque psoriasis
- psoriatic arthritis in adults
- Crohn's disease in adults
- paediatric Crohn's disease.

Pyzchiva® 45 mg and 90 mg solution for injection in pre-filled pen (PFP) and pre-filled syringe (PFS) are on the HSE Reimbursement List, for prescribing and supply on the High Tech Arrangement.

Hospital pricing approval is in place for Pyzchiva® 130 mg concentrate for solution for infusion vial.

Pyzchiva® is a biosimilar medicine. This means that Pyzchiva® is highly similar to another biological medicine (the reference medicine) that is already authorised in the European Union. The reference medicine for Pyzchiva® is Stelara®.

This product information sheet provides information to support clinical teams when prescribing the PFP and PFS presentations of Pyzchiva® for patients. The Summary of Product Characteristics (SmPC) for Pyzchiva® should be referred to for full prescribing information. This product information sheet does not contain information in relation to the concentrate for solution for infusion vial presentation of Pyzchiva®.

[a] ▼This medicinal product is subject to additional monitoring.
[b] Please refer to the Summary of Product Characteristics of Pyzchiva® for full prescribing information.

Pyzchiva® solution for injection in pre-filled pen

Pyzchiva® 45 mg pre-filled pen **Pyzchiva® 90 mg pre-filled pen**

- Each Pyzchiva® 45 mg PFP contains 45 mg of ustekinumab in 0.5 millilitres (mL) solution for injection.
- Each Pyzchiva® 90 mg PFP contains 90 mg of ustekinumab in 1.0 mL solution for injection.
- Each pack contains one single-use PFP.
- There is no latex present in the PFP; Pyzchiva® PFP is therefore suitable for patients with a latex allergy.
- It is supplied as a clear, colourless to light yellow solution for injection. The solution may contain a few small translucent or white particles of protein.
- The PFP is equipped with a 29-gauge needle.

Storage

- Pyzchiva® PFP should be stored in a refrigerator (2°C - 8°C). It should not be frozen. It should not be used if it is, or has been, frozen.
- The PFP should be kept in the outer carton in order to protect it from light.
- If needed, an individual PFP may be stored at room temperature up to 30°C for a maximum single period of up to 35 days in the original carton in order to protect from light. Record the date when the PFP is first removed from the refrigerator and the discard date in the spaces provided on the outer carton. At any time before the end of this 35-day period, the PFP can be put back into the refrigerator once and kept there until the expiry date. Discard the PFP if not used after the maximum period of 35 days at room temperature or by the original expiry date, whichever is earlier.

Dose Administration

- The patient information leaflet contains instructions in both text and diagrammatic form, on how to administer a dose from a Pyzchiva® PFP. This should be used as the primary source of information in relation to administration of Pyzchiva® PFP.
- The PFP presentation of Pyzchiva® has not been studied in the paediatric population and is not recommended for use in paediatric patients.
- Each Pyzchiva® PFP is for single-use only.
- Before administration, the solution in the Pyzchiva® PFP should be visually inspected for particulate matter or discolouration. The solution is clear, colourless to light yellow and may contain a few small translucent or white particles of protein. This appearance is not unusual for proteinaceous solutions. Pyzchiva® PFP should not be used if the solution is discoloured or cloudy, or if foreign particulate matter is present.
- The PFP should not be shaken.
- Before administration, the PFP should be removed from the refrigerator and let stand outside the box for about half an hour, to allow the solution to reach room temperature.
- Delivery of the dosage commences when the patient pushes the PFP firmly onto their skin, at a 90-degree angle; an initial click may be heard when the injection begins.
- The patient should continue to press the PFP down onto the skin until the yellow indicator stops moving. The injection may take up to 10 seconds.

- A second click may be heard. This means the injection is finished.
- While holding the PFP in place, the viewing window should be checked to ensure it has turned yellow; this indicates the full dose has been administered and the empty PFP can be removed from the skin.
- The needle guard will slide down and cover the needle.

Similarities between Pyzchiva® pre-filled pen and the reference biological medicine (Stelara® pre-filled pen)

- Pyzchiva® PFP and Stelara® PFP are licensed for the treatment of: [c]
    - plaque psoriasis in adults
    - psoriatic arthritis in adults
    - Crohn's disease in adults.
- Pyzchiva® PFP and Stelara® PFP are single-use PFPs.
- Pyzchiva® PFP and Stelara® PFP should not be shaken.
- Pyzchiva® PFP and Stelara® PFP should be stored in a refrigerator (2°C - 8°C), and should not be frozen.
- Pyzchiva® PFP and Stelara® PFP should be kept in the outer carton in order to protect from light.
- Both Pyzchiva® and Stelara® PFP presentations have a safety feature to guard the needle upon delivery of the dose of ustekinumab, with a passive needle guard system in place, i.e. upon administration of the dose of ustekinumab, the entire needle covered by the needle safety guard.
- Both Pyzchiva® and Stelara® PFP presentations have features to assist the patient in identifying that administration of the dose of ustekinumab is complete:
    - for Pyzchiva® PFP, the viewing window turns yellow
    - for Stelara® PFP, the purple body is not visible and you cannot press the handle down anymore.

Differences between Pyzchiva® pre-filled pen and the reference biological medicine (Stelara® pre-filled pen)

- Pyzchiva® PFP is not licensed for the treatment of ulcerative colitis; Stelara® PFP is licensed for the treatment of ulcerative colitis in adults.
- Pyzchiva® PFP has a shelf life of 42 months and Stelara® PFP have a shelf life of three years.
- Pyzchiva® PFP is fitted with a 29-gauge needle; Stelara® PFP is fitted with a 27-gauge needle. Both are small gauge needles, with the small difference unlikely to cause a difference in practice.
- There is no latex present in the Pyzchiva® PFP; the needle cover inside the bottom cap of Stelara® PFP is manufactured from dry natural rubber, which is a derivative of latex.
- In terms of storage of an individual PFP at room temperature:
    - Pyzchiva® PFP: an individual PFP may be stored at room temperature up to 30°C for a maximum single period of up to 35 days in the original carton in order to protect from light. At any time before the end of this 35-day period, the PFP can be put back into the refrigerator once and kept there until the expiry date. The PFP should be discarded if not used after the maximum period of 35 days at room temperature or by the original expiry date, whichever is earlier.
    - Stelara® PFP: an individual PFP may be stored at room temperature up to 30°C for a maximum single period of up to 30 days in the original carton in order to protect from light. Once a Stelara® PFP has been stored at room temperature (up to 30°C), it should not be returned to the refrigerator. The PFP should be discarded if not used within 30 days at room temperature storage or by the original expiry date, whichever is earlier.

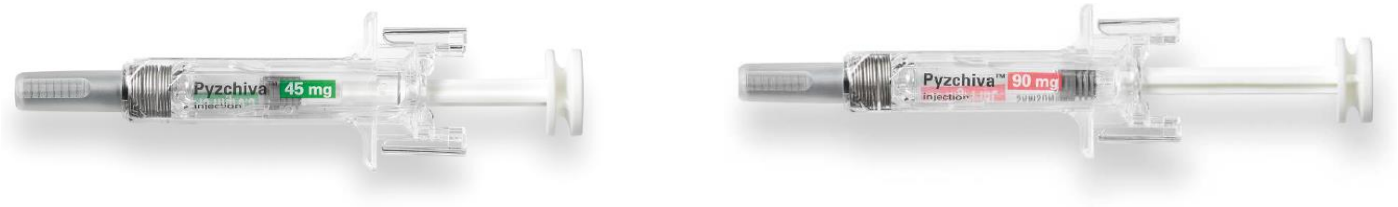
[c]Please refer to the Summary of Product Characteristics of Pyzchiva® for full prescribing information.


Pyzchiva™ 45 mg
solution for injection in pre-filled pen
ustekinumab
45 mg/0.5 mL
Subcutaneous use
1 pre-filled pen
Pyzchiva™ 45 mg
ustekinumab


Pyzchiva™ 90 mg
solution for injection in pre-filled pen
ustekinumab
90 mg/1 mL
Subcutaneous use
1 pre-filled pen
Pyzchiva™ 90 mg
ustekinumab

Pyzchiva® solution for injection in pre-filled syringe

Pyzchiva® 45 mg pre-filled syringe **Pyzchiva® 90 mg pre-filled syringe**



- Each Pyzchiva® 45 mg PFS contains 45 mg of ustekinumab in 0.5 mL solution for injection.
- Each Pyzchiva® 90 mg PFS contains 90 mg of ustekinumab in 1.0 mL solution for injection.
- Each pack contains one single-use PFS.
- There is no latex present in the PFS; Pyzchiva® PFS is therefore suitable for patients with a latex allergy.
- It is supplied as a clear, colourless to light yellow solution for injection. The solution may contain a few small translucent or white particles of protein.
- The PFS is equipped with a 29-gauge needle.

Storage

- Pyzchiva® PFS should be stored in a refrigerator (2°C - 8°C). It should not be frozen. It should not be used if it is, or has been, frozen.
- The PFS should be kept in the outer carton in order to protect it from light.
- If needed, an individual PFS may be stored at room temperature up to 30°C for a maximum single period of up to 35 days in the original carton in order to protect from light. Record the date when the PFS is first removed from the refrigerator and the discard date in the spaces provided on the outer carton. At any time before the end of this 35-day period, the PFS can be put back into the refrigerator once and kept there until the expiry date. Discard the PFS if not used after the maximum period of 35 days at room temperature or by the original expiry date, whichever is earlier.

Dose Administration

- The patient information leaflet contains instructions in both text and diagrammatic form, on how to administer a dose from a Pyzchiva® PFS. This should be used as the primary source of information in relation to administration of Pyzchiva® PFS.
- Each Pyzchiva® PFS is for single-use only.
- Before administration, the solution in the Pyzchiva® PFS should be visually inspected for particulate matter or discolouration. The solution is clear, colourless to light yellow and may contain a few small translucent or white particles of protein. This appearance is not unusual for proteinaceous solutions. Pyzchiva® PFS should not be used if the solution is discoloured or cloudy, or if foreign particulate matter is present.
- The PFS should not be shaken.
- Before administration, the PFS should be removed from the refrigerator and let stand outside the box for about half an hour, to allow the solution to reach room temperature.
- The ensure the full dosage of ustekinumab is administered, push the plunger until the plunger head is completely between the needle guard wings.
- Upon release of the plunger having administered the dosage of ustekinumab, the entire needle is drawn back automatically and covered by the needle safety guard.

Similarities between Pyzchiva® pre-filled syringe and the reference biological medicine (Stelara® pre-filled syringe)

- Pyzchiva® PFS and Stelara® PFS are licensed for the treatment of:[d]
    - plaque psoriasis in adults
    - paediatric plaque psoriasis
    - psoriatic arthritis in adults
    - Crohn's disease in adults
    - paediatric Crohn's disease.
- Pyzchiva® PFS and Stelara® PFS are single-use PFS.
- Pyzchiva® PFS and Stelara® PFS should not be shaken.
- Pyzchiva® PFS and Stelara® PFS should be stored in a refrigerator (2°C - 8°C), and should not be frozen.
- Pyzchiva® PFS and Stelara® PFS should be kept in the outer carton in order to protect from light.
- Both Pyzchiva® and Stelara® PFS presentations have a safety feature to guard the needle upon delivery of the dose of ustekinumab, with a passive needle guard system in place, i.e. upon release of the plunger having administered the dose, the entire needle is drawn back automatically and covered by the needle safety guard.

Differences between Pyzchiva® pre-filled syringe and the reference biological medicine (Stelara® pre-filled syringe)

- Pyzchiva® PFS is not licensed for the treatment of ulcerative colitis; Stelara® PFS is licensed for the treatment of ulcerative colitis in adults.
- Pyzchiva® PFS has a shelf life of 42 months and Stelara® PFS have a shelf life of three years.
- Pyzchiva® PFS is fitted with a 29-gauge needle; Stelara® PFS is fitted with a 27-gauge needle. Both are small gauge needles, with the small difference unlikely to cause a difference in practice.
- There is no latex present in the Pyzchiva® PFS; the needle cover on the syringe of Stelara® PFS is manufactured from dry natural rubber, which is a derivative of latex.
- In terms of storage of an individual PFS at room temperature:
    - Pyzchiva® PFS: an individual PFS may be stored at room temperature up to 30°C for a maximum single period of up to 35 days in the original carton in order to protect from light. At any time before the end of this 35-day period, the PFS can be put back into the refrigerator once and kept there until the expiry date. The PFS should be discarded if not used after the maximum period of 35 days at room temperature or by the original expiry date, whichever is earlier.
    - Stelara® PFS: an individual PFS may be stored at room temperature up to 30°C for a maximum single period of up to 30 days in the original carton in order to protect from light. Once a Stelara® PFS has been stored at room temperature (up to 30°C), it should not be returned to the refrigerator. The PFS should be discarded if not used within 30 days at room temperature storage or by the original expiry date, whichever is earlier.

[d]Please refer to the Summary of Product Characteristics of Pyzchiva® for full prescribing information.


Pyzchiva™
45 mg
solution for injection in pre-filled syringe
ustekinumab
45 mg/0.5 mL
Subcutaneous use
1 pre-filled syringe
For single use only.
Each pre-filled syringe contains
45 mg of ustekinumab in 0.5 mL.
OPEN


Pyzchiva™
90 mg
solution for injection in pre-filled syringe
ustekinumab
90 mg/1 mL
Subcutaneous use
1 pre-filled syringe
For single use only.
Each pre-filled syringe contains
90 mg of ustekinumab in 1 mL.
OPEN

Sandoz Limited trading as Rowex Patient Support Services

Sandoz Limited trading as Rowex provide a patient support programme to patients who have been prescribed Pyzchiva®. This is provided by Hibernian Healthcare at Home on behalf of Sandoz Limited trading as Rowex.

The following services are available at no charge to patients prescribed Pyzchiva® following a referral by their prescriber:

- Provision of up to two nurse home visits to deliver patient education and training on correct injection and administration technique. This can be delivered remotely, if required.
- Sharps management service – this includes supply, collection and disposal of a sharps bin
- Post-home visit report shared with the referring healthcare professional
- Access to a helpline for queries
- Provision of a patient support pack, which includes a step-by-step administration guide, an injection tracker diary to record administration dates and information on travelling with Pyzchiva®
- Provision of faecal calprotectin home test kits to gastroenterology patients
- Provision of Quantiferon testing
- Provision of testing panel for Hepatitis B Surface antibodies and surface antigen, Hepatitis B Core antibodies and Hepatitis C antibodies.

In order to avail of the patient support services for patients who have been prescribed Pyzchiva®, please use the Hibernian Healthcare at Home online portal https://schedule.hahirl.com/.

If you have not registered on the Hibernian Healthcare at Home online portal previously, please contact Hibernian Healthcare at Home at 01 460 4792 or by email at info@hibernianhealth.com, and access and support will be provided.

Sandoz Limited trading as Rowex provide a variety of resources to healthcare professionals to aid patient education, including injection demonstration devices for both the PFP and PFS presentations for training.

In order to obtain patient support materials for use in clinics, please contact:

- Email: info@hibernianhealth.com
- Phone: 01 460 4792

Pyzchiva is a registered trademark of Samsung Bioepis Co., Ltd.

References:

1. Samsung Bioepis NL B.V. Pyzchiva® 45 mg solution for injection in pre-filled syringe, Pyzchiva® 90 mg solution for injection in pre-filled syringe, Pyzchiva® 45 mg solution for injection in pre-filled pen, Pyzchiva® 90 mg solution for injection in pre-filled pen. Summary of Product Characteristics. Last updated 21/11/2025. Accessed at: https://www.ema.europa.eu/en/medicines/human/EPAR/pyzchiva on 15/12/2025.
2. Janssen-Cilag International NV. Stelara® 45 mg solution for injection in prefilled syringe, Stelara® 90 mg solution for injection in pre-filled syringe, Stelara® 45 mg solution for injection in pre-filled pen, Stelara® 90 mg solution for injection in pre-filled pen. Summary of Product Characteristics. Last updated 14/04/2025. Accessed at: https://www.ema.europa.eu/en/medicines/human/EPAR/stelara on 15/12/2025.