

Best-Value Biological Medicine (Ustekinumab): Wezenla®

Information for Healthcare Professionals

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

Prescribing Wezenla® 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 Wezenla®▼^{a,b} are recommended as best-value biological (BVB) medicines:

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

Wezenla® 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.

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

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

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

This product information sheet provides information to support clinical teams when prescribing the PFP, PFS and solution for injection vial presentations of Wezenla® for patients. The Summary of Product Characteristics (SmPC) for Wezenla® 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 Wezenla®.

^a▼ This medicinal product is subject to additional monitoring.

^bPlease refer to the Summary of Product Characteristics of Wezenla® for full prescribing information.

Wezenla® solution for injection in pre-filled pen

Wezenla® 45 mg pre-filled pen



Wezenla® 90 mg pre-filled pen



- Each Wezenla® 45 mg PFP contains 45 mg of ustekinumab in 0.5 millilitres (mL) solution for injection.
- Each Wezenla® 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; Wezenla® PFP is therefore suitable for patients with a latex allergy.
- It is supplied as a clear to opalescent, colourless to light yellow solution for injection.
- The PFP is equipped with a 27-gauge needle.

Storage

- Wezenla® 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 30 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. Once a Wezenla® 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.

Dose Administration

- The patient information leaflet contains instructions in both text and diagrammatic form, on how to administer a dose from a Wezenla® PFP. This should be used as the primary source of information in relation to administration of Wezenla® PFP.
- The PFP presentation of Wezenla® has not been studied in the paediatric population and is not recommended for use in paediatric patients.
- Each Wezenla® PFP is for single-use only.
- Before administration, the solution in the Wezenla® PFP should be visually inspected for particulate matter or discolouration. The solution is clear to opalescent, colourless to light yellow. Wezenla® 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 down firmly onto their skin, at a 90-degree angle; an initial click may be heard or felt when the injection begins.
- The patient should continue to press the PFP down onto the skin until the indicator window turns fully yellow. The injection may take up to 15 seconds to complete.
- A second click may be heard or felt.

- 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 Wezenla® pre-filled pen and the reference biological medicine (Stelara® pre-filled pen)

- Wezenla® PFP and Stelara® PFP are licensed for the treatment of:^c
 - plaque psoriasis in adults
 - psoriatic arthritis in adults
 - Crohn's disease in adults.
- Wezenla® PFP and Stelara® PFP are single-use PFPs.
- Wezenla® PFP and Stelara® PFP should not be shaken.
- Wezenla® PFP and Stelara® PFP have a shelf life of three years.
- Wezenla® PFP and Stelara® PFP should be stored in a refrigerator (2°C - 8°C), and should not be frozen.
- Wezenla® PFP and Stelara® PFP should be kept in the outer carton in order to protect from light.
- For both Wezenla® and Stelara®, 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 Wezenla® PFP or 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.
- Wezenla® PFP and Stelara® PFP are both fitted with a 27-gauge needle.
- Both Wezenla® 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 PFP presentations have features to assist the patient in identifying that administration of the dose of ustekinumab is complete:
 - for Wezenla® 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 Wezenla® pre-filled pen and the reference biological medicine (Stelara® pre-filled pen)

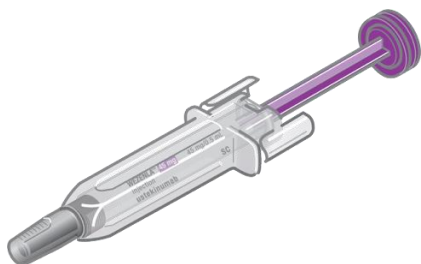
- Wezenla® PFP is not licensed for the treatment of ulcerative colitis; Stelara® PFP is licensed for the treatment of ulcerative colitis in adults.
- There is no latex present in the Wezenla® PFP; the needle cover inside the bottom cap of Stelara® PFP is manufactured from dry natural rubber, which is a derivative of latex.



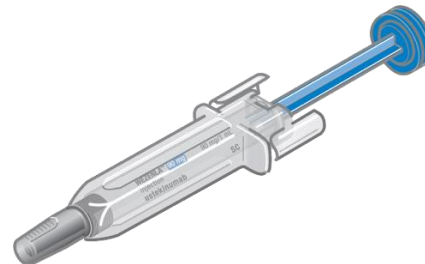
^cPlease refer to the Summary of Product Characteristics of Wezenla® for full prescribing information.

Wezenla® solution for injection in pre-filled syringe

Wezenla® 45 mg pre-filled syringe



Wezenla® 90 mg pre-filled syringe



- Each Wezenla® 45 mg PFS contains 45 mg of ustekinumab in 0.5 mL solution for injection.
- Each Wezenla® 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; Wezenla® PFS is therefore suitable for patients with a latex allergy.
- It is supplied as a clear to opalescent, colourless to light yellow solution for injection.
- The PFS is equipped with a 27-gauge needle.

Storage

- Wezenla® 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 30 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. Once a Wezenla® 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.

Dose Administration

- The patient information leaflet contains instructions in both text and diagrammatic form, on how to administer a dose from a Wezenla® PFS. This should be used as the primary source of information in relation to administration of Wezenla® PFS.
- Each Wezenla® PFS is for single-use only.
- Before administration, the solution in the Wezenla® PFS should be visually inspected for particulate matter or discolouration. The solution is clear to opalescent, colourless to light yellow. Wezenla® 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.
- To 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 Wezenla® pre-filled syringe and the reference biological medicine (Stelara® pre-filled syringe)

- Wezenla® 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.
- Wezenla® PFS and Stelara® PFS are single-use PFS.
- Wezenla® PFS and Stelara® PFS should not be shaken.
- Wezenla® PFS and Stelara® PFS have a shelf life of three years.
- Wezenla® PFS and Stelara® PFS should be stored in a refrigerator (2°C - 8°C), and should not be frozen.
- Wezenla® PFS and Stelara® PFS should be kept in the outer carton in order to protect from light.
- For both Wezenla® and Stelara®, 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 Wezenla® PFS or 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.
- Wezenla® PFS and Stelara® PFS are both fitted with a 27-gauge needle.
- Both Wezenla® 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 Wezenla® pre-filled syringe and the reference biological medicine (Stelara® pre-filled syringe)

- Wezenla® PFS is not licensed for the treatment of ulcerative colitis; Stelara® PFS is licensed for the treatment of ulcerative colitis in adults.
- There is no latex present in the Wezenla® PFS; the needle cover on the syringe of Stelara® PFS is manufactured from dry natural rubber, which is a derivative of latex.



^dPlease refer to the Summary of Product Characteristics of Wezenla® for full prescribing information.

Wezenla® solution for injection vial presentation



- Each Wezenla® vial contains 45 mg ustekinumab in 0.5 mL solution for injection.
- Each pack contains one single-use glass vial.
- It is supplied as a clear to opalescent, colourless to light yellow solution for injection.
- The vial presentation of Wezenla® facilitates subcutaneous administration for the treatment of plaque psoriasis in paediatric patients weighing less than 45 kilograms, who need to receive less than a 45 mg dose of ustekinumab.

Storage

- Wezenla® vial 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 vial should be kept in the outer carton in order to protect it from light.
- If needed, an individual unopened vial 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. Record the date when the vial is first removed from the refrigerator and the discard date. Once a Wezenla® vial has been stored at room temperature (up to 30°C), it should not be returned to the refrigerator. The vial should be discarded if not used within 30 days at room temperature storage or by the original expiry date, whichever is earlier.
- After withdrawing the solution for injection in a disposable syringe, the SmPC states that the chemical and physical in-use stability has been demonstrated for 24 hours at 15°C to 25°C; this should not be returned to the refrigerator during this time. The SmPC also states that, from a microbiological point of view, the product should be used immediately; if it is not used immediately, the in-use storage times and conditions are the responsibility of the user.

Dose Administration

- The patient information leaflet contains instructions in both text and diagrammatic form, on how to administer a dose from a Wezenla® vial. This should be used as the primary source of information in relation to administration of Wezenla® vial.
- Each Wezenla® vial is for single-use only.
- Before administration, the solution in the Wezenla® vial should be visually inspected for particulate matter or discolouration. The solution is clear to opalescent, colourless to light yellow. Wezenla® vial should not be used if the solution is discoloured or cloudy, or if foreign particulate matter is present.
- The vial should not be shaken.
- Before administration, the vial 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.

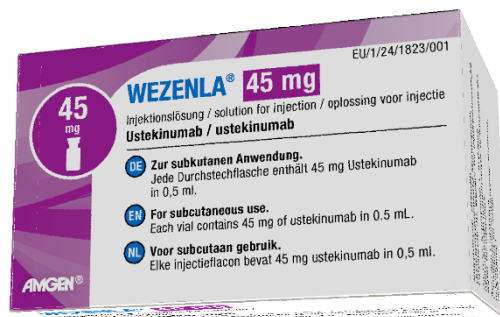
- The ancillaries required for administration of the solution by subcutaneous injection are not provided with Wezenla® vial. The SmPC of Wezenla® recommends a 1 mL syringe with a 27-gauge, ½ inch (13 millimetres) needle when administering a dosage subcutaneously.

Similarities between Wezenla® 45 mg vial and the reference biological medicine (Stelara® 45 mg vial)

- Wezenla® vial and Stelara® vial are both single-use vials.
- Wezenla® vial and Stelara® vial should not be shaken.
- Wezenla® vial and Stelara® vial should be stored in a refrigerator (2°C - 8°C), and should not be frozen.
- Wezenla® vial and Stelara® vial should be kept in the outer carton in order to protect from light.
- The ancillaries required for administration of the solution by subcutaneous injection are not provided with Wezenla® vial or Stelara® vial. The SmPC of both recommend a 1 mL syringe with a 27-gauge, ½ inch (13 millimetres) needle when administering a dosage subcutaneously.

Differences between Wezenla® 45 mg vial and the reference biological medicine (Stelara® 45 mg vial)

- Wezenla® vial has a shelf life of three years and Stelara® vial has a shelf life of two years.



Amgen Ireland Limited Patient Support Services

Amgen Ireland Limited provide a patient support programme to patients who have been prescribed Wezenla®. This is provided by Hibernian Healthcare at Home and TCP Homecare on behalf of Amgen Ireland Limited.

The following services are available at no charge to patients prescribed Wezenla® following referral:

- 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
- Text messenger reminder service to aid adherence to medication
- Provision of an Amgen Care support pack, which includes a patient information booklet and information on how to access further patient resources via the Amgen Care website, including an online tutorial video on how to inject Wezenla®
- Provision of faecal calprotectin home test kits to gastroenterology patients
- Provision of Quantiferon testing.

In order to avail of the patient support services for patients who have been prescribed Wezenla®, please use the Hibernian Healthcare at Home online portal

<https://schedule.hahirl.com/> or the TCP Homecare online portal <https://tcphomecareportal.ie/>.

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.

If you have not registered on the TCP Homecare online portal previously, please contact TCP Homecare at 1800 211 211 or by email at homecare.PCB@tcp.ie, and access and support will be provided.

Amgen Ireland Limited provide a variety of resources to healthcare professionals to aid patient education, including patient guides and injection demonstration devices for training.

In order to obtain training pens and patient support materials for use in clinics, please contact the relevant provider:

Hibernian Healthcare at Home

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

TCP Homecare

- Email: homecare.PCB@tcp.ie
- Phone: 1800 211 211

References:

1. Amgen Technology (Ireland) UC. Wezenla® 45 mg solution for injection , Wezenla® 45 mg solution for injection in pre-filled syringe, Wezenla® 90 mg solution for injection in pre-filled syringe Wezenla® 45 mg solution for injection in pre-filled pen, Wezenla® 90 mg solution for injection in pre-filled pen. Summary of Product Characteristics. Last updated 11/08/2025. Accessed at: <https://www.ema.europa.eu/en/medicines/human/EPAR/Wezenla> on 15/12/2025.
2. Janssen-Cilag International NV. Stelara® 45 mg solution for injection, 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 prefilled 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.