

Best-Value Biological Medicine (Ustekinumab): Imuldosa®

Information for Healthcare Professionals

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

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

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

Imuldosa® is licensed for the treatment of:^b

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

The pre-filled syringe (PFS) presentation of Imuldosa® containing 45 mg or 90 mg of ustekinumab is on the HSE Reimbursement List, for prescribing and supply on the High Tech Arrangement.

Hospital pricing approval is in place for the 130 mg concentrate for solution for infusion vial presentation of Imuldosa®.

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

This product information sheet provides information to support clinical teams when prescribing the PFS presentation of Imuldosa® for patients. The Summary of Product Characteristics (SmPC) for Imuldosa® 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 Imuldosa®.

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

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

Imuldosa® solution for injection in pre-filled syringe

Imuldosa® 45 mg pre-filled syringe



Imuldosa® 90 mg pre-filled syringe



- Each Imuldosa® 45 mg PFS contains 45 mg of ustekinumab in 0.5 millilitres (mL) solution for injection.
- Each Imuldosa® 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; Imuldosa® PFS is therefore suitable for patients with a latex allergy.
- It is supplied as a colourless to slightly yellow and clear to slightly opalescent solution for injection.
- The PFS is equipped with a 29-gauge needle.

Storage

- Imuldosa® 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 in the spaces provided on the outer carton. The discard date must not exceed the original expiry date printed on the carton. Once a PFS has been stored at room temperature (up to 30°C), it should not be returned to the refrigerator. Discard the syringe 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 an Imuldosa® PFS. This should be used as the primary source of information in relation to administration of Imuldosa® PFS.
- Each Imuldosa® PFS is for single-use only.
- Before administration, the solution in the Imuldosa® PFS should be visually inspected for particulate matter or discolouration. Only a solution that is colourless to slightly yellow and clear to slightly opalescent should be used. Imuldosa® 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.

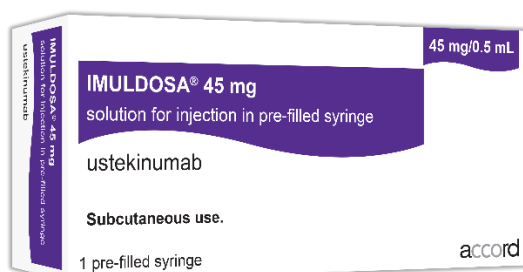
Similarities between Imuldosa® pre-filled syringe and the reference biological medicine (Stelara® pre-filled syringe)

- Imuldosa® PFS and Stelara® PFS are licensed for the treatment of:^c
 - plaque psoriasis in adults
 - paediatric plaque psoriasis
 - psoriatic arthritis in adults
 - Crohn's disease in adults.
- Imuldosa® PFS and Stelara® PFS are single-use PFS.
- Imuldosa® PFS and Stelara® PFS should not be shaken.
- Imuldosa® PFS and Stelara® PFS have a shelf life of three years.
- Imuldosa® PFS and Stelara® PFS should be stored in a refrigerator (2°C - 8°C), and should not be frozen.
- Imuldosa® PFS and Stelara® PFS should be kept in the outer carton in order to protect from light.
- For both Imuldosa® 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 an Imuldosa® 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.
- Both Imuldosa® 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.

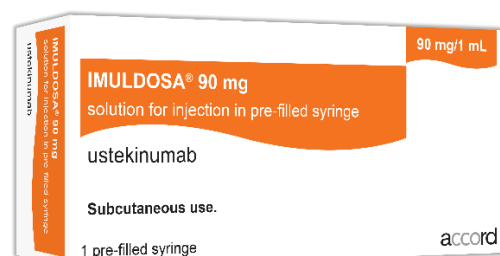
Differences between Imuldosa® pre-filled syringe and the reference biological medicine (Stelara® pre-filled syringe)

- Imuldosa® PFS is not licensed for the treatment of ulcerative colitis or paediatric Crohn's disease; Stelara® PFS is licensed for the treatment of ulcerative colitis in adults and paediatric Crohn's disease.
- Imuldosa® 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 Imuldosa® PFS; the needle cover on the syringe of Stelara® PFS is manufactured from dry natural rubber, which is a derivative of latex.

Imuldosa® 45 mg pre-filled syringe packaging



Imuldosa® 90 mg pre-filled syringe packaging



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

Accord Healthcare Ireland Limited Patient Support Services

Accord Healthcare Ireland Limited provide a patient support programme to patients who have been prescribed Imuldosa®. This is provided by Hibernian Healthcare at Home on behalf of Accord Healthcare Ireland Limited.

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

- Provision of up to two nurse home visits to deliver patient education and training on correct injection and administration technique for Imuldosa®; a third visit can be provided if required on a triage basis. 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 compliance phone call at a pre-determined time interval to aid adherence
- Provision of patient support materials, e.g. patient guide to Imuldosa®, patient diary, online tutorial video on how to inject Imuldosa®
- Provision of faecal calprotectin home test kits to gastroenterology patients.

In order to avail of the patient support services for patients who have been prescribed Imuldosa®, 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.

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

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

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

References:

1. Accord Healthcare S.L.U. Imuldosa® 45 mg solution for injection in pre-filled syringe, Imuldosa® 90 mg solution for injection in pre-filled syringe. Summary of Product Characteristics. Last updated 24/06/2025. Accessed at: <https://www.ema.europa.eu/en/medicines/human/EPAR/imuldosa> 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. 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.