# Best-Value Biological Medicine (Ustekinumab): Otulfi®

## Information for Healthcare Professionals

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

**Prescribing Otulfi® 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 Otulfi®▼[a,b] are recommended as best-value biological (BVB) medicines:

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

Otulfi® 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.

The pre-filled syringe (PFS) presentation of Otulfi® 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 Otulfi®.

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

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

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

**Otulfi® solution for injection in pre-filled syringe**

**Otulfi® 45 mg pre-filled syringe**


**Otulfi® 90 mg pre-filled syringe**


- Each Otulfi® 45 mg pre-filled syringe (PFS) contains 45 mg of ustekinumab in 0.5 millilitres (mL) solution for injection.
- Each Otulfi® 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; Otulfi® PFS is therefore suitable for patients with a latex allergy.
- It is supplied as a clear to slightly opalescent, colourless to light brown-yellow solution for injection. The solution may contain a few translucent or white particles of protein.
- The PFS is equipped with a 29-gauge needle.

***Storage***

- Otulfi® 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 Otulfi® PFS. This should be used as the primary source of information in relation to administration of Otulfi® PFS.
- Each Otulfi® PFS is for single-use only.
- Before administration, the solution in the Otulfi® PFS should be visually inspected for particulate matter or discolouration. The solution is clear to slightly opalescent, colourless to light brown-yellow and may contain a few translucent or white particles of protein. This appearance is not unusual for proteinaceous solutions. Otulfi® 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 Otulfi® pre-filled syringe and the reference biological medicine (Stelara® pre-filled syringe)*

- Otulfi® 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
    - paediatric Crohn's disease
- Otulfi® PFS and Stelara® PFS are single-use PFS.
- Otulfi® PFS and Stelara® PFS should not be shaken.
- Otulfi® PFS and Stelara® PFS have a shelf life of three years.
- Otulfi® PFS and Stelara® PFS should be stored in a refrigerator (2°C - 8°C), and should not be frozen.
- Otulfi® PFS and Stelara® PFS should be kept in the outer carton in order to protect from light.
- For both Otulfi® 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 Otulfi® 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 Otulfi® 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 Otulfi® pre-filled syringe and the reference biological medicine (Stelara® pre-filled syringe)*

- Otulfi® PFS is not licensed for the treatment of ulcerative colitis; Stelara® PFS is licensed for the treatment of ulcerative colitis in adults.
- Otulfi® 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 Otulfi® PFS; the needle cover on the syringe of Stelara® PFS is manufactured from dry natural rubber, which is a derivative of latex.

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

## Fresenius Kabi Ireland Patient Support Services

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

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

- Provision of nurse home visits to deliver patient education and training on correct injection and administration technique. No strict limit is applied in terms of the number of visits. 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
- Follow-up service to aid adherence to medication
- Provision of an Otulfi® patient kit, which includes a patient information guide and information on how to access further online patient resources including an injection technique instruction video
- 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 Otulfi®, 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.**

Fresenius Kabi Ireland provide a variety of resources to healthcare professionals to aid patient education, including injection demonstration devices for training.

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

- Email: stuart.mackenzie-smith@fresenius-kabi.com
- Phone: (087) 353 2622

**References:**


1. Fresenius Kabi Deutschland GmbH. Otulfi® 45 mg solution for injection in pre-filled syringe, Otulfi® 90 mg solution for injection in pre-filled syringe. Summary of Product Characteristics. Last updated 11/09/2025. Accessed at: https://www.ema.europa.eu/en/medicines/human/EPAR/Otulfi 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.