

Best-Value Biological Medicine (Filgrastim): Accofil®

Information for Healthcare Professionals

The MMP recommends Accofil® as a Best-Value Biological (BVB) Medicine for filgrastim on the High Tech Arrangement.

Prescribing Accofil® reduces the financial burdens 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 Accofil®¹, available on the High Tech Arrangement, are recommended as best-value biological (BVB) medicines:

- Accofil® solution for injection (SFI) pre-filled syringe (PFS) 30 million units (MU)/0.5 millilitres (mL)
- Accofil® SFI PFS 48 MU/0.5 mL.

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

Accofil® solution for injection pre-filled syringe

Accofil® SFI PFS 30 MU/0.5 mL



Accofil® SFI PFS 48 MU/0.5 mL



- Each Accofil® SFI PFS 30 MU/0.5 mL contains 30 MU (300 micrograms [mcg]) of filgrastim in 0.5 mL solution.
- Each Accofil® SFI PFS 48 MU/0.5 mL contains 48 MU (480 mcg) of filgrastim in 0.5 mL solution.
- Accofil® SFI PFS is formulated as a clear, colourless solution for injection or concentrate for solution for infusion.
- The needle cover of the PFS contains dry natural rubber (a derivative of latex), which may cause allergic reactions.

¹ Please refer to the Summary of Product Characteristics (SmPC) for Accofil® for full prescribing information.

Storage

- Accofil® SFI PFS should be stored in a refrigerator (2°C - 8°C).
- Accofil® PFS should not be frozen. Accidental one-time exposure to freezing temperatures does not adversely affect its stability; if the exposure is greater than 48 hours, or if the medicinal product is frozen more than once, then the Accofil® PFS should not be used.
- The PFS should be kept in the outer carton of the packaging in order to protect from light.
- The PFS may be removed from the refrigerator and stored at room temperature (not above 25°C) for one single period of up to 15 days. At the end of this period, the PFS should not be put back in the refrigerator and should be disposed of.
- Accofil® SFI PFS does not contain a preservative. It is, therefore, for single use only in view of the possible risk of microbial contamination.

Dose Administration – Subcutaneous Injection

- Before use, the solution for injection in Accofil® PFS should be inspected visually. Only clear solutions without particles should be used.
- The PFS should not be shaken.
- For a more comfortable injection, the PFS should be left to stand for 30 minutes to reach room temperature or held in the patient's hand for a few minutes. The PFS should not be warmed in any other way.
- The patient information leaflet and SmPC include detailed instructions on how to administer a dose from the PFS, including a diagrammatic guide. This should be consulted prior to administration of Accofil® PFS.
- The syringe barrel of Accofil® PFS is marked in 0.025 mL graduations from 0.1 mL to 1.0mL. Each PFS contains 0.5 mL solution for injection.
- The dose of filgrastim to be injected should be checked prior to administration. The PFS may contain more liquid than needed. Use the scale on the syringe barrel as follows to set the correct dose of Accofil® that has been prescribed:
 - Eject unnecessary liquid by pushing the plunger up to the volume (mL) on the PFS that matches the prescribed dose.
- The plunger rod must be pushed down firmly at the end of the injection to ensure that emptying of the PFS is completed.
- The needle safety guard system will activate once the plunger rod is fully depressed. The patient should keep the PFS still and slowly lift their thumb from the plunger rod head. The plunger rod will move up their thumb and the spring will retract the needle from the site, into the needle safety guard.
- Following administration, the Accofil® PFS should be disposed of as instructed by a healthcare professional.

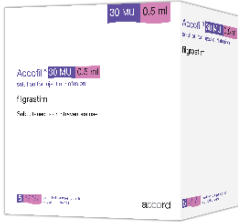
Similarities between Accofil® PFS and the reference biological medicine (Neupogen® PFS)

- Accofil® PFS has a shelf life of three years; Neupogen® PFS has a shelf life of 36 months.
- Accofil® PFS and Neupogen® PFS contain a 27-gauge needle.
- The needle covers of Accofil® and Neupogen® contain dry natural rubber, which may cause allergic reactions.

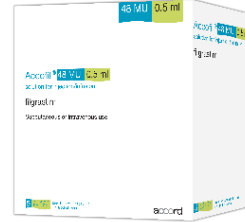
Differences between Accofil® PFS and the reference biological medicine (Neupogen® PFS)

- Accofil® PFS contains a safety feature to guard the needle upon delivery of the dose of filgrastim; there is no safety feature in place for Neupogen® PFS.
- The syringe barrel of Accofil® PFS is marked in 0.025 mL graduations from 0.1 mL to 1.0 mL (note: each PFS contains 0.5 mL solution). The syringe barrel of Neupogen® PFS is marked in 0.1 mL graduations from 0.1 mL to 0.5 mL

Accofil® SFI PFS 30 MU/0.5 mL



Accofil® SFI PFS 48 MU/0.5 mL



Accord Healthcare Ireland Limited Patient Support Services

Accord Healthcare Ireland Limited provide a patient support service to patients who have been prescribed Accofil®. Hibernian Healthcare at Home provides this service on behalf of Accord Healthcare Ireland Limited.

The following services are available as part of the patient support service:

- Sharps management service – this includes supply, collection and disposal of a sharps bin
- Access to a helpline for patient queries (01 460 4820)
- Provision of patient support materials, e.g. patient guide to Accofil®, patient diary.
- In exceptional circumstances, to support patients with a specific identified need, nurses can deliver patient education and training on correct injection and administration technique for Accofil®. Please contact your local Accord Healthcare Ireland Limited representative for further information.

In order to avail of the sharps management service for patients who have been prescribed Accofil®, please use the Hibernian Healthcare at Home online portal <https://schedule.hahirl.com>.

If you have not registered on the Hibernian portal previously, please contact Hibernian Healthcare at Home at 01 460 4820 or by email at patientqueries@hibernianhealth.com, and access and support will be provided.

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

- Email: patientqueries@hibernianhealth.com
- Phone: 01 460 4820

References:

1. Accord Healthcare S.L.U. Accofil® 30 MU/0.5 mL solution for injection or infusion in pre-filled syringe, Accofil® 48 MU/0.5 mL solution for injection or infusion in pre-filled syringe. Summary of Product Characteristics. Last revised 30/08/2024. Accessed at www.ema.europa.eu on 28/04/2025.
2. Amgen Europe B.V. Neupogen® Singleject 30 MU/0.5 mL solution for injection in prefilled syringe, Neupogen® Singleject 48 MU/0.5 mL solution for injection in prefilled syringe. Summary of Product Characteristics. Last revised 29/04/2024. Accessed at www.hpra.ie on 28/04/2025.