Best-Value Biological Medicine (Long-acting granulocyte-colony stimulating factors): Pelgraz® (Pegfilgrastim)

Information for Healthcare Professionals

The MMP recommends Pelgraz® as a Best-Value Biological (BVB) Medicine for the long-acting granulocyte-colony stimulating factors. Prescribing Pelgraz® will lead to significant savings for the health service.

The following presentations of Pelgraz®, available on the High Tech Arrangement, are recommended as best-value biological (BVB) medicines:

- Pelgraz® solution for injection pre-filled injector (PFI) 6 mg/0.6 ml
- Pelgraz® solution for injection pre-filled syringe (PFS) 6 mg/0.6 ml.

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

Pelgraz® solution for injection pre-filled injector 6 mg/0.6 ml

- Each pack contains one PFI, containing 6 mg of pegfilgrastim.
- The PFI contains a PFS externally equipped with a device for self-administration.
- It is supplied as a clear, colourless solution for injection.
- The needle cover of the PFS within the PFI contains dry natural rubber (a derivative of latex), which may cause allergic reactions.

Storage

- Pelgraz® PFI should be stored in a refrigerator (2°C - 8°C). It should not be frozen. Accidental exposure to freezing temperatures for a single period of less than 24 hours does not adversely affect its stability.
- The PFI should be kept in the original packaging in order to protect it from light.
- The PFI may be exposed to room temperature (not above 25°C ± 2°C) for a maximum single period of up to 15 days. It should be discarded if left at room temperature for longer than 15 days.

Dose Administration

- Before use, the solution for injection in Pelgraz® PFI should be inspected visually for particulate matter. Only a solution that is clear and colourless should be injected.
- The PFI should be allowed to reach room temperature for 30 minutes before injecting.
- Excessive shaking of the PFI should be avoided as it may aggregate pegfilgrastim, rendering it biologically inactive.
- The patient information leaflet contains a clear diagrammatic guide on how to administer a dose from the PFI.
- Delivery of the dose of pegfilgrastim commences when the patient pushes the handle on the PFI straight down. The PFI should not be lifted of the skin during injection.
- Administration of a dose of pegfilgrastim from the PFI is complete when the handle has been pushed down as far as possible. A click will be heard and the orange body on the handle will no longer be visible.
- Upon administration of the dose of pegfilgrastim, the needle in the PFI is covered by a needle guard. The appearance of the yellow band indicates that the needle guard is locked.

Similarities between Pelgraz® PFI and the reference biological medicine (Neulasta® PFS)

- Pelgraz® PFI and Neulasta® PFS have a shelf life of three years.
- Pelgraz® PFI and Neulasta® PFS contain a 27-gauge needle.
- The needle covers of Pelgraz® and Neulasta® contain dry natural rubber, which may cause allergic reactions.
- Pelgraz® PFI and Neulasta® PFS have a safety feature to guard the needle upon delivery of a dose of pegfilgrastim.

Differences between Pelgraz® PFI and the reference biological medicine (Neulasta® PFS)

- Pelgraz® PFI may be exposed to room temperature (not above 25°C ± 2°C) for a maximum single period of up to 15 days. It should be discarded if left at room temperature for longer than 15 days. Neulasta® PFS may be exposed to room temperature (not above 30°C) for a maximum single period of up to 72 hours.

Pelgraz® solution for injection pre-filled syringe 6 mg/0.6 ml

- Each pack contains one PFS, containing 6 mg of pegfilgrastim.
- It is supplied as a clear, colourless solution for injection.
- The needle cover of the PFS contains dry natural rubber (a derivative of latex), which may cause allergic reactions.

Storage

- Pelgraz® PFS should be stored in a refrigerator (2°C - 8°C). It should not be frozen. Accidental exposure to freezing temperatures for a single period of less than 24 hours does not adversely affect its stability.
- The PFS should be kept in the original packaging in order to protect it from light.
- The PFS may be exposed to room temperature (not above 25°C ± 2°C) for a maximum single period of up to 15 days. It should be discarded if left at room temperature for longer than 15 days.

Dose Administration

- Before use, the solution for injection in Pelgraz® PFS should be inspected visually for particulate matter. Only a solution that is clear and colourless should be injected.
- The PFS should be allowed to reach room temperature for 30 minutes before injecting.
- Excessive shaking of the PFS should be avoided as it may aggregate pegfilgrastim, rendering it biologically inactive.
- The patient information leaflet contains a clear diagrammatic guide on how to administer a dose from the PFS.
- The plunger rod must be pushed down firmly at the end of the injection to ensure that the full dose of pegfilgrastim is delivered.
- 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.

Similarities between Pelgraz® PFS and the reference biological medicine (Neulasta® PFS)

- Pelgraz® PFS and Neulasta® PFS have a shelf life of three years.
- Pelgraz® PFS and Neulasta® PFS contain a 27-gauge needle.
- The needle covers of Pelgraz® and Neulasta® contain dry natural rubber, which may cause allergic reactions.
- Pelgraz® PFS and Neulasta® PFS have a safety feature to guard the needle upon delivery of a dose of pegfilgrastim.

Differences between Pelgraz® PFS and the reference biological medicine (Neulasta® PFS)

- Pelgraz® PFS may be exposed to room temperature (not above 25°C ± 2°C) for a maximum single period of up to 15 days. It should be discarded if left at room temperature for longer than 15 days. Neulasta® PFS may be exposed to room temperature (not above 30°C) for a maximum single period of up to 72 hours.

Accord Healthcare Ireland Limited Patient Support Services

Accord Healthcare Ireland Limited provide a patient support service to patients who have been prescribed Pelgraz®. 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:

- Provision of up to two nurse home visits to deliver patient education and training on correct injection and administration technique for Pelgraz®; 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
- Provision of follow-up phone call at time of initial self-administration of Pelgraz®
- Access to a helpline for patient queries
- Provision of patient support materials, e.g. patient guide to Pelgraz®, patient diary, online tutorial video on how to inject Pelgraz®
- Access to the Pelgraz® Patient App. This includes a dose reminder alarm, online tutorial video on how to inject Pelgraz®, information on neutropenia and a patient diary to record symptoms.

In order to avail of the patient support services for patients who have been prescribed Pelgraz ®, please use the Hibernian Healthcare at Home online portal www.schedule.hahirl.com. If you have not registered on the Hibernian 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.

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

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

References:

1. Pelgraz® 6 mg/0.6 ml solution for injection in pre-filled pen/pre-filled injector. Summary of Product Characteristics. Last revised 15/09/2023. Accessed at www.ema.europa.eu on 11/03/2024.