

Best-Value Medicine (Teriparatide): Sondelbay®

Information for Healthcare Professionals

The MMP recommends Sondelbay® as a Best-Value Medicine (BVM) for teriparatide. Prescribing Sondelbay® will lead to significant savings for the health service.

The following presentation of Sondelbay®▼¹, available on the High Tech Arrangement, is recommended as a best-value medicine (BVM):

- Sondelbay® 20 micrograms (mcg)/80 microliters solution for injection in pre-filled pen (PFP)

Sondelbay® pre-filled pen



- Each pack contains one disposable PFP.
- Each dose that the PFP delivers contains 20 mcg of teriparatide in 80 microliters.
- Each PFP contains 28 doses of 20 mcg of teriparatide.
- There is no latex present in the PFP; Sondelbay® PFP is therefore suitable for patients with a latex allergy.
- It is supplied as a colourless, clear solution.

Storage

- Sondelbay® 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 original outer package in order to protect it from light.
- Once opened, a Sondelbay® PFP may be stored for a maximum of 28 days at 2°C - 8°C (i.e. in a refrigerator).
- The Sondelbay® PFP should be disposed of after 28 days from the date of first administration, even if it is not completely empty.
- Sondelbay® PFP can be stored at temperature conditions up to 25°C for a maximum of three days when refrigeration is not available, after which it should be returned to the refrigerator and used within 28 days of the first injection.
- The Sondelbay® PFP should be discarded if it has been kept out of the refrigerator, at temperatures up to 25°C for more than three days.

¹ ▼ This medicinal product is subject to additional monitoring

Dose Administration

- The Pen User Manual within the patient information leaflet contains a very clear diagrammatic guide on how to administer a dose from the PFP.
- Each Sondelbay® PFP should be used by one patient only.
- Sondelbay® PFP should not be used if the solution is cloudy, coloured or contains particles.
- Sondelbay® PFP does not require priming prior to administration of the first dose from the PFP.
- A new, sterile needle must be used when administering each dose of teriparatide from the Sondelbay® PFP.
- Needles are not supplied with the Sondelbay® PFP and therefore they should be prescribed and dispensed separately.
- Sondelbay® PFP can be used with pen needles (31 G or 32 G; 4 mm, 5 mm or 8 mm); these should be prescribed in conjunction with the Sondelbay® PFP.
- Sondelbay® PFP should be recapped when not in use to protect it from physical damage and light.
- The needle should be removed and placed in a sharps bin after administration of each dose of teriparatide. Sondelbay® PFP should not be stored with a needle attached.
- The date of administration of the first injection from a Sondelbay® PFP should be written in the provided space (*date of first use*) on the outer packaging.
- There is a dose counter on the Sondelbay® PFP; it displays the number of doses remaining in the PFP.
- When administration of a dose of teriparatide from the Sondelbay® is complete, an empty circle sign will appear in the dose setting window; if the empty circle sign does not appear, a second dose should not be administered on the same day. Instead, the Sondelbay® PFP should be reset. Information on how to reset the PFP is available in the Pen User Manual.

Similarities between Sondelbay® PFP and the reference biological medicine (Forsteo® PFP)

- Sondelbay® PFP and Forsteo® PFP have a shelf life of two years.
- After administration of the first injection from the PFP, both Sondelbay® PFP and Forsteo® PFP should be stored for a maximum of 28 days at 2°C - 8°C, after which time they should be disposed of, even if they are not completely empty.
- Both Sondelbay® PFP and Forsteo® PFP do not require priming prior to administration of the first dose from the PFPs.
- A new, sterile needle must be used when administering each dose of teriparatide from both Sondelbay® PFP and Forsteo® PFP.
- Needles are not supplied with the Sondelbay® PFP or Forsteo® PFP.
- Both Sondelbay® PFP and Forsteo® PFP are disposable PFPs; the PFP and its contents are discarded 28 days after administration of the first injection from the PFP. A new PFP is then supplied to the patient.

Differences between Sondelbay® PFP and the reference biological medicine (Forsteo® PFP)

- Sondelbay® PFP can be stored at temperature conditions up to 25°C for a maximum of three days when refrigeration is not available, after which it should be returned to the refrigerator and used within 28 days of the first injection. Forsteo® PFP must be stored in a refrigerator (2°C - 8°C) at all times.
- Sondelbay® PFP contains a dose counter that displays the number of doses remaining in the PFP. There is no dose counter in the Forsteo® PFP.
- Sondelbay® PFP and Forsteo® PFP have different indicators to show that administration of a dose of teriparatide is complete; for Sondelbay®, an empty circle sign will appear in the dose setting window. For Forsteo®, the black injection button should be all the way in, and the yellow shaft should not be visible.



Accord Healthcare Ireland Limited Patient Support Services

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

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

- Nurse home visit: Provision of up to three nurse home visits to deliver patient education and training on correct injection and administration technique for Sondelbay® PFP.
- Sharps management service: This includes the provision of sharps bins and waste collection.
- Post-home visit education report shared with the referring healthcare professional
- Provision of follow-up support phone calls
- Provision of patient support materials, e.g. patient guide to Sondelbay® and online tutorial video on Sondelbay® administration.

In order to avail of the patient support services for patients who have been prescribed Sondelbay®, 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. Sondelbay® 20 micrograms/80 microliters solution for injection in pre-filled pen. Summary of Product Characteristics. Last revised 16/06/2022. Accessed at www.ema.europa.eu on 01/02/2023.