

DIRECT HEALTHCARE PROFESSIONAL COMMUNICATION

Sondelbay▼ (teriparatide) solution for injection in a pre-filled pen Interim Supply of Polish Stock to Mitigate Supply Disruption

Dear Healthcare Professional,

Summary: Accord-Healthcare Limited is currently experiencing supply disruption with Sondelbay (teriparatide) 20mcg/80mcl solution for injection in a pre-filled pen in the UK

To ensure continuity in supply, Accord-Healthcare has obtained approval from the MHRA to supply Polish product (batch number 8540001; 494 packs) which is expected to be in the UK market from mid-late May 2025.

Please note the following:

- Equivalent product is licensed in the UK.
- The product from Poland has the same formulation as the UK product
- The product from Poland is manufactured according to the same manufacturing process and quality controls as the UK product.
- There are minor differences between the Polish and UK product information. Please ensure the UK Summary of Product Characteristics (SPC) and Patient Information Leaflet (PIL) and the IFU leaflet are followed. QR codes for the SmPC and PIL can be found at the end of this letter.
- For additional copies of the leaflet, please refer to the QR codes below.
- The MHRA has agreed to an exemption granted in accordance with regulation 266(4)(a) and (b) of the Human Medicines Regulations (HMR) 2012, from the obligation that certain particulars should appear on the outer and immediate packaging of Sondelbay and that the information must be given in English .

Please ensure all relevant staff are made aware of the content of this letter and that the information is communicated to the patients.



Image not to scale

Call for reporting

Please continue to report suspected adverse drug reactions (ADRs) to the MHRA through the Yellow Card scheme.

Please report:

- all suspected ADRs that are serious or result in harm. Serious reactions are those that are fatal, life-threatening, disabling or incapacitating, those that cause a congenital abnormality or result in hospitalisation, and those that are considered medically significant for any other reason
- all suspected ADRs associated with new drugs and vaccines identified by the black triangle ▼

You can report via:

- the [Yellow Card website](#)
- the free Yellow Card app available from the Apple App Store or Google Play Store
- some clinical IT systems (EMIS/SystemOne/Vision/MiDatabank) for healthcare professionals

Alternatively, you can report a suspected side effect to the Yellow Card scheme by calling 0800 731 6789 for free, Monday to Friday between 9am and 5pm.

When reporting please provide as much information as possible, including information about medical history, any concomitant medication, timing onset, treatment dates, and product brand name.

Sondelbay ▼ is subject to additional monitoring. This will allow quick identification of new safety Information.

Please report ANY suspected adverse drug reactions (ADRs) to drugs and vaccines identified by the black triangle ▼ to the MHRA through the Yellow Card Scheme.

The non-identical nature of biological medicines and vaccines means it is very important that safety surveillance is carried out on a brand/product-specific basis. When reporting a suspected ADR to a biological medicine (such as blood products, antibodies and advanced therapies [such as gene and tissue therapy]) or vaccine, please ensure that you provide the brand name (or product licence number and manufacturer), and the specific batch-number.

Additionally, when providing patients with details of the vaccine or biological medicine administered, it is good practice to give them details of the brand and batch number. This will allow patients and carers to more accurately report suspected ADRs to the Yellow Card scheme.

Company contact point

If you have any questions about this letter or require more information about Sondelbay, please contact Accords' Medical Information at medinfo@accord-healthcare.com or telephone 01271 385257

Yours faithfully,

[Signature]

[Named staff member]

[Job title]

Please Scan

Sondelbay (teriparatide) SmPC



Sondelbay (teriparatide) PIL

