Recordati Rare Diseases UK Ltd
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Date: 24 Jun 2026

DIRECT HEALTHCARE PROFESSIONAL COMMUNICATION

Pedea 5 mg/ml solution for injection [PLGB 15266/0024]: Interim Supply of Multi-Language European Stock Including English-Language Product Information to Mitigate Supply Disruption

Dear Healthcare Professional,

Summary: Recordati Rare Diseases UK Ltd is currently experiencing supply disruption with Pedea 5 mg/ml solution for injection [PLGB 15266/0024].

To ensure continuity in supply, Recordati Rare Diseases UK Ltd has obtained approval from the Medicines and Healthcare products Regulatory Agency (MHRA) to supply Multi-Language European Stock Including English-Language Product Literature:

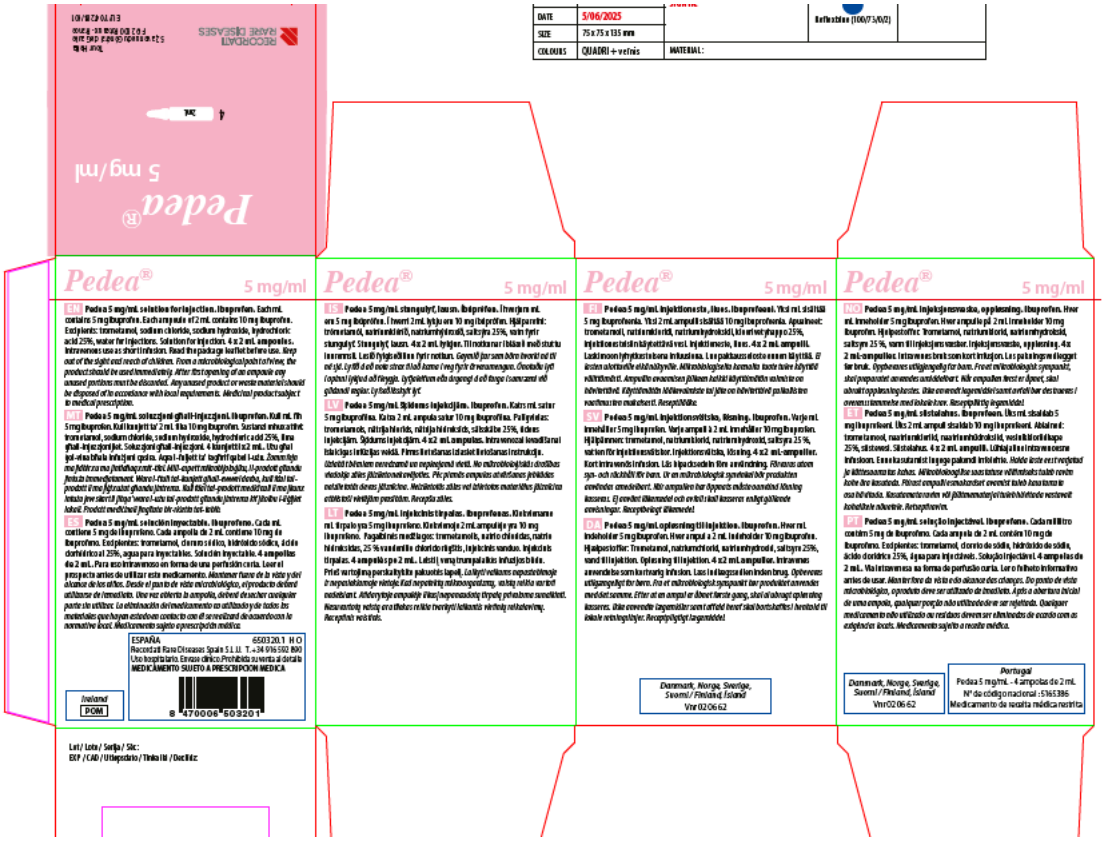
Pedea 5 mg/ml solution for injection [PLGB 15266/0024] (batch number P2402EX01; **import of 499 boxes** out of batch total of 499 boxes).
This batch was released for sale in Denmark, Estonia, Finland, Iceland, Ireland, Latvia, Lithuania, Malta, Norway, Portugal, Spain, Sweden.

Please note the following:

- This product is licensed in the UK.
- The product from Denmark, Estonia, Finland, Iceland, Ireland, Latvia, Lithuania, Malta,
- Norway, Portugal, Spain, Sweden has the same formulation as the UK product
- The product from Denmark, Estonia, Finland, Iceland, Ireland, Latvia, Lithuania, Malta,
- Norway, Portugal, Spain, Sweden is manufactured according to the same manufacturing process and quality controls as the UK product.
- Please ensure the UK Summary of Product Characteristics (SPC) and Patient Information Leaflet (PIL) are referred to and followed. SPC and PIL will be provided electronically.
- Discard the multi-language PIL in the pack.
- For additional copies of the leaflet, please refer to https://www.medicines.org.uk/emc/product/11587/pil
- 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 Pedea 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.

Packs of Pedea 5mg/ml to be supplied (Multi-language pack)



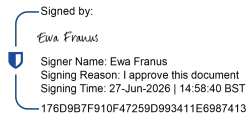
Call for reporting

Healthcare professionals are asked to report any suspected adverse reactions to the Yellow Card Scheme electronically. Report via the website https://www.gov.uk/yellowcard, the free Yellow Card app available from the Apple App Store or Google Play Store, and some clinical IT systems (EMIS, SystmOne, Vision, MiDatabank) for healthcare professionals. Suspected side effect can also be reported by calling 0800 731 6789 for free.

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

Company contact point
If you have any questions about this letter, or require more information about Pedea, please contact Recordati Rare Diseases UK Ltd at Breakspear Park, Hemel Hempstead, HP2 4TZ, United Kingdom or telephone +44 (0)1491 414 333 or email orders.uk@recordati.com

Adverse events should be reported. (UK) Reporting forms and information can be found at https://yellowcard.mhra.gov.uk/. Adverse events should also be reported to Recordati Rare Diseases UK Ltd by telephone: +44 (0)1491 414 333 or email RRDpharmacovigilance@recordati.com.



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Ewa Franus
Responsible Person

Recordati Rare Diseases UK Ltd
Breakspear Park, Hemel Hempstead, HP2 4TZ, United Kingdom