

19 October 2023

Diazepam Desitin 5 mg Rectal solution: Interim Supply of Dutch Labelled Tubes to Mitigate Supply Disruption

Dear Healthcare professional,

Desitin Arzneimittel GmbH in agreement with the Medicines and Healthcare products Regulatory Agency (MHRA) would like to inform you of the following:

Summary

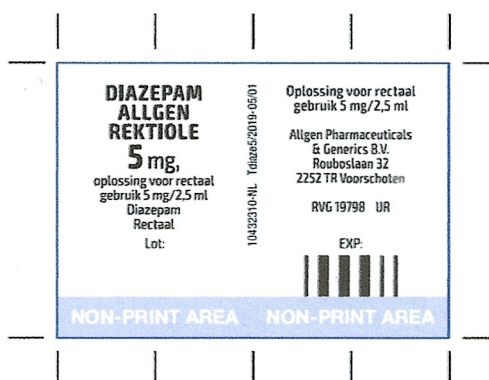
- To help support continuity in supply, Desitin has obtained approval from the MHRA to temporarily supply to the UK market (Great Britain and Northern Ireland) Diazepam Desitin 5 mg Rectal solution in packs which have primary packaging (i.e. the tube itself) printed in the Dutch language. The foil pack, carton and Patient Information Leaflet (PIL) will be the approved English-language versions.

Please note the following:

- We expect these packs to be on the UK market from mid of November 2023 until end of January 2024.
- This product is considered licenced in the UK.
- The product from the Netherlands has the same formulation as the UK product.
- The product from the Netherlands is manufactured according to the same manufacturing process and quality controls as the UK product.
- Please refer to the UK approved Patient Information Leaflet (PIL) supplied with the pack.
- For additional copies of the leaflet, please refer to <https://www.medicines.org.uk/emc/product/2997/pil> or contact the company contact point (see below).
- The MHRA has agreed to an exemption granted in accordance with regulation 266(4)(a) of the Human Medicines Regulations (HMR) 2012 for supply to Great Britain and according to Article 63(3) of Council Directive 2001/83/EC for supply to Northern Ireland.

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

Example of Dutch labelled tubes and corresponding labelling text:



Call for reporting

Healthcare professionals are asked to report any suspected adverse drug reactions (ADRs) to the Yellow Card scheme electronically.

Report via the website <https://yellowcard.mhra.gov.uk/>, the free Yellow Card app available from the Apple App Store or Google Play Store, and some clinical IT systems (EMIS/SystemOne/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, timing onset, treatment dates, and product brand name.

Company contact point

If you have any questions about this letter or wish more information about Diazepam Desitin Rectal solution, please contact Desitin Pharma Ltd, Fairbourne Drive, Atterbury, Milton Keynes, Buckinghamshire, MK10 9RG or telephone +44 (0) 1908 488817 or medinfo@desitin.co.uk.

Yours faithfully,



Andy Stewart
UK Country Manager
Desitin Pharma Ltd