

06 March 2024

**DIRECT HEALTHCARE PROFESSIONAL COMMUNICATION**

**Diazepam Desitin 10 mg Rectal solution (PL 14040/0002):  
Caps harder to remove than usual**

Dear Healthcare Professional/Carer,

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

**Summary**

- Due to production reasons, the cap of the emergency medication Diazepam Desitin 10 mg Rectal solution sits unusually tightly on the tip of the tube and may require additional force to remove. This issue is currently under investigation and steps are being taken to resolve this for future batches. To ensure continuity in supply and avoid out of stock situations, Desitin Arzneimittel GmbH will continue to supply affected batches to the UK market (Great Britain and Northern Ireland) in the meantime.

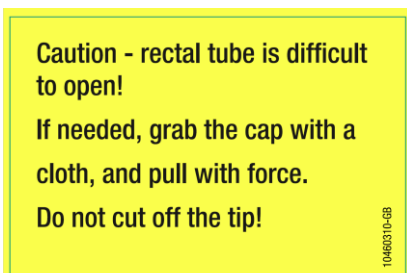
Please note the following:

- The quality and effectiveness of the medicine itself are not affected.
- Batches of rectal tubes that are difficult to open have an appropriate warning sticker on the packaging.
- To ensure the correct and quick application of the medication, please be aware of the following:
  - The cap of the rectal tubes is harder to remove than usual.
  - The cap should be grasped **at the edge of the cap**, if necessary with a cloth, and then pulled off with force.
  - **The tip of the rectal tube must under no circumstances be cut off**, otherwise there is a risk of injury from the sharp cutting edge when used.

**Instructions for Pharmacists**

- When dispensing tubes from the affected batches, please advise users about how to remove the caps as described above.
- Please ensure all relevant staff are made aware of the content of this letter and that the information is communicated to patients/carers.

Example of warning sticker:



### ***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.

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.

### ***Company contact point***

If you have any questions about this letter, or for all medical information enquiries and information on this product, please contact Desitin Pharma Ltd, Fairbourne Drive, Atterbury, Milton Keynes, Buckinghamshire, MK10 9RG or telephone +44 (0)1908 488817 or [medinfo@desitin.co.uk](mailto:medinfo@desitin.co.uk).

Yours faithfully,



Andy Stewart  
Managing Director  
Desitin Pharma Ltd