

DIRECT HEALTHCARE PROFESSIONAL COMMUNICATION

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

BEROMUN® 1mg, Powder for solution for infusion (Tasonermin- EU license number: EU/1/99/097/001):

Interim Supply of German Stock to Mitigate Supply Disruption

Dear Healthcare Professional,

To ensure continuity in supply, Belpharma s.a. has obtained approval from the MHRA to supply Beromun® product in German pack (batch number 96275-1; 1 pack) which is expected to be on the UK market from September 2026 to November 2026.

This importation of Beromun® was requested by the **Royal Marsden hospital** in London, who urgently needs to use this product for a patient. The intervention is scheduled for 30-September-2026.

Please note the following:

- This product is considered licensed in the UK.
- The product from Germany has the same formulation as the UK product
- The product from Germany is manufactured according to the same manufacturing process and quality controls as the UK product.
- There are no differences between the German and UK product information and packaging.
- A multilingual leaflet, including English, is provided with the pack.
- 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 Beromun® 1mg and that the information must be given in English .

Call for reporting

Please 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 website <https://www.gov.uk/yellowcard>
- 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 require more information about Beromun® 1mg, please contact Belpharma s.a at office@belpharma.lu.

Yours faithfully,

Elmira BAJELAN
Clinical and Technical Manager
Belpharma s.a