



Orion Pharma UK Ltd
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DIRECT HEALTHCARE PROFESSIONAL COMMUNICATION

Dexdor 100 micrograms/ml concentrate for solution for infusion (Dexmedetomidine): Interim Supply of ROI/NI (EU license) Stock to Mitigate Supply Disruption

Dear Healthcare Professional,

Summary: Orion Pharma (UK) Ltd is currently experiencing supply disruption with Dexdor 100 micrograms/ml concentrate for solution for infusion (Dexmedetomidine) in Great Britain.

To ensure continuity in supply, Orion Pharma (UK) Ltd has obtained approval from the MHRA to supply ROI/NI (EU license) product (batch number is 2214562 x 324 packs), which is expected to be on the UK (Great Britain) market from 23/08/2024 to 31/10/2024 (dates are a best estimate based on current stock levels, anticipated orders and estimated delivery schedule).

Please note the following:

- This product is considered licensed in Great Britain (GB). The GB license was grandfathered from the EU license.
- The EU license product has the same formulation as the GB-licensed product.
- The EU-licensed product is manufactured according to the same manufacturing process and quality controls as the GB-licensed product.
- The licenses are aligned (the GB license was grandfathered from the EU license). The only differences are:
 - Deviation between the EU and GB PIL - The EU PIL states that an increased mortality risk has been seen for patients 65 years of age and under when using this medicine, in comparison to the GB PIL which does not state this. This deviation has been discussed with the MHRA Vigilance Service & Data Provision Team and it is the MAH's intention to align the EU PIL with the GB PIL once the necessary data is available.
 - EU PIL contains EU-specific details, e.g. Northern Ireland/Ireland adverse event reporting and local representative details, reference to the European Medicines Agency web site.
 - EU license number included on outer carton of EU license packaging.
- Please ensure the GB Summary of Product Characteristics (SPC) is followed.
- For copies of the GB leaflet, please refer to www.medicines.org.uk/emc/files/pil.4783.pdf or contact the company contact point (see 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 Dexdor 100 micrograms/ml concentrate for solution for infusion 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.

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/SystemsOne/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 Dexdor 100 micrograms/ml concentrate for solution for infusion, please contact Orion Pharma (UK) Ltd Medical Information at Orion Pharma UK Ltd, Abbey Gardens, 4 Abbey Street, Reading, Berks, RG1 3BA or telephone +44 (0) 1635 520300 or via <https://www.orionpharma.co.uk/>

Yours faithfully,



Charles De Wet
Head of Medical, UK and Ireland
Orion Pharma UK Ltd