

Date: 27 April 2020

DIRECT HEALTHCARE PROFESSIONAL COMMUNICATION

Midazolam 1mg/ml Solution for Injection or Infusion (Midazolam): Interim Supply of French Stock to Mitigate Supply Disruption

Dear Healthcare Professional,

Summary: Accord-UK Ltd is currently experiencing supply disruption with Midazolam 1mg/ml Solution for Injection or Infusion (Midazolam) in the UK.

To ensure continuity in supply during the current Covid-19 situation, Accord Healthcare has obtained approval from the MHRA to supply French product (batch numbers X15438 (5,470 packs), X16043 (5,148 packs), X16573 (5,130 packs), and X16574 (5,310 packs); which are expected to be on the UK market from April to October 2020.

Please note the following:

- This product is considered licensed in the UK.
- The product from France has the same formulation as the UK product.
- The product from France is manufactured according to the same manufacturing process and relevant quality controls as the UK product.
- There are minor differences between the French and UK product information. Please ensure the UK Summary of Product Characteristics (SPC) and Patient Information Leaflet (PIL) are followed.
- Please refer to the UK approved PIL supplied with each order of the French packs. Discard the French leaflet in the pack.
- For additional copies of the leaflet, please refer to <https://www.medicines.org.uk/emc/> or contact the company contact point (see below).
- The MHRA has approved this product under a batch specific variation to the marketing authorisation.

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

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 wish more information about Midazolam 1mg/ml Solution for Injection or Infusion, please contact Accord-UK Ltd Medical Information at medinfo@accord-healthcare.com or telephone +44 (0) 1271 385257 or Accord-UK Ltd, Whiddon Valley, Barnstaple, Devon, EX32 8NS, UK.

Mark L King
Director, Quality Operations (QP/RP)