

Date: 15 May 2020

### **DIRECT HEALTHCARE PROFESSIONAL COMMUNICATION**

## Clozaril 25 mg tablets (clozapine): Interim Supply of Danish and Swedish Stock to Mitigate Supply Disruption

Dear Healthcare Professional,

# Summary: Mylan is currently experiencing supply disruption with Clozaril 25 mg tablets (clozapine) in the UK.

Due to unavoidable circumstances related to the current Covid-19 situation, there has been a delivery delay to our next consignment of Clozaril 25mg x 100 tablet bottles. To ensure continuity in supply during this period of disruption, Mylan has obtained approval from the MHRA to supply Danish and Swedish product:

Batch Number	Quantity (no. of packs)	Expiry	Origin
HR2239	523	30/07/2020	Denmark
8088851	789	31/05/2022	Sweden
8098261	450	30/09/2022	Sweden

### Please note the following:

- This product is considered licensed in the UK.
- The product from Denmark and Sweden has the same formulation as the UK product. The tablets are identical in appearance.
- The product from Denmark and Sweden is manufactured according to the same manufacturing process and quality controls as the UK product.
- There are differences between the Danish, Swedish and UK product information. The language is different and the Danish and Swedish brand name is Leponex, not Clozaril.
- This product is strictly limited for use in dosette boxes and pill organisers and should not be dispensed in the Danish or Swedish packs to patients.
- Please ensure the UK Summary of Product Characteristics (SPC) and Patient Information Leaflet (PIL) are followed.
- Please refer to the UK approved PIL supplied electronically with the Danish and Swedish packs. Discard the Danish and Swedish leaflets in the pack.
- For additional copies of the leaflet, please refer to <a href="https://www.medicines.org.uk/emc/">https://www.medicines.org.uk/emc/</a> or contact the company contact point (see below).
- The MHRA has approved this product under a batch specific variation to the marketing authorisation.
- Blister packs remain available to service patient prescriptions, where appropriate.



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

# Danish carton Vnr 03 06 35 Leponex® 25 mg tabletter/töflur clozapin. 100 tabl./töflur



### **Call for reporting**

Healthcare professionals are asked to report any suspected adverse reactions to the Yellow Card Scheme electronically. Report via the website <a href="https://www.gov.uk/yellowcard">https://www.gov.uk/yellowcard</a>, the free Yellow Card app available from the <a href="https://www.gov.uk/yellowcard">Apple App Store</a> or <a href="https://www.gov.uk/yellowcard">Google Play Store</a>, 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. Adverse events should also be reported to Mylan via CPMS@mylan.co.uk

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 Clozaril, please contact Julian De Gabriele, Mylan UK Healthcare Limited (078 7602 0133) or CPMS@mylan.co.uk