

Date: 25 Oct 2022

**DIRECT HEALTHCARE PROFESSIONAL COMMUNICATION**

**Zonegran® 100 mg hard capsules**

**Zonegran® 25 mg hard capsules**

**Zonegran® 50 mg hard capsules**

**EU/1/04/307/001-013**

**Interim Supply of EU Stock to Mitigate Supply Disruption**

Dear Healthcare Professional,

**Summary: Mercury Pharmaceuticals Limited is currently experiencing supply disruption with Zonegran 25mg/50mg/100mg capsules in the UK(NI).**

To ensure continuity of supply, Mercury Pharmaceuticals Limited has obtained approval from the MHRA to supply below mentioned Irish batches which is expected to be placed on the UKNI market from October 2022 to July 2023.

Name of the product	Batch Number	Number of Packs
Zonegran 100mg Caps	TP00325	10,857
Zonegran 25mg Caps	TP00246	888
Zonegran 25mg Caps	TP00329	7422
Zonegran 50mg Caps	TP00262	1293
Zonegran 50mg Caps	TP00289	4104

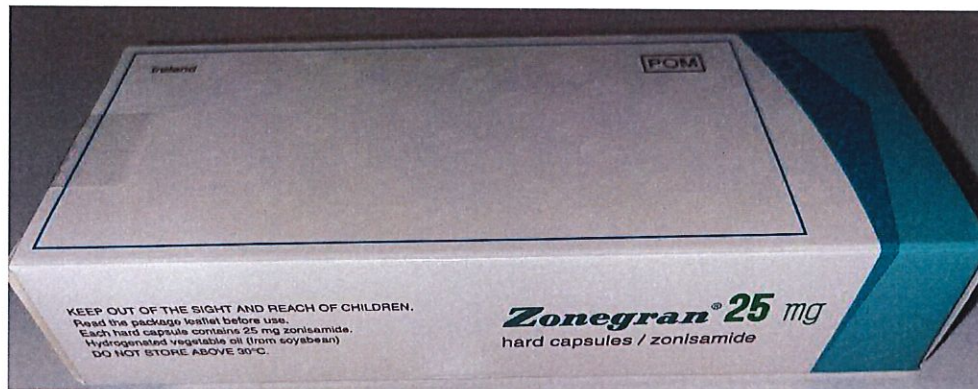
Please note the following:

- This product is considered licensed in the UK (Northern Ireland).
- The product from EU has the same formulation as the UK (Northern Ireland) product
- The product from EU is manufactured according to the same manufacturing process and quality controls as the UK(NI) product.
- The only difference between the EU and the UK (Northern Ireland) product information is that the member state United Kingdom (Northern Ireland) is not mentioned as a country on the EU carton as per Blue Box requirements.
- There are no changes to the UK(NI) Summary of Product Characteristics (SPC) and Patient Information Leaflet (PIL).
- The MHRA has agreed to an exemption according to Article 63(3) of Council Directive 2001/83/EC, from the obligation that certain particulars should appear on the outer and immediate packaging of Zonegran 25mg/50mg/100mg capsules and that the information must be given in English.

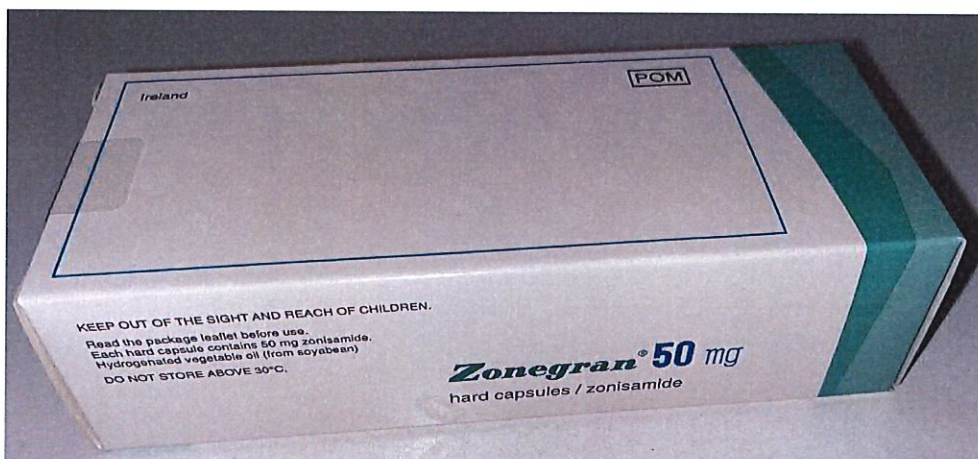
Please ensure all relevant staff are made aware of the content of this letter and that the information is communicated to the patients.

Please see below snapshot of the cartons to be exempted:

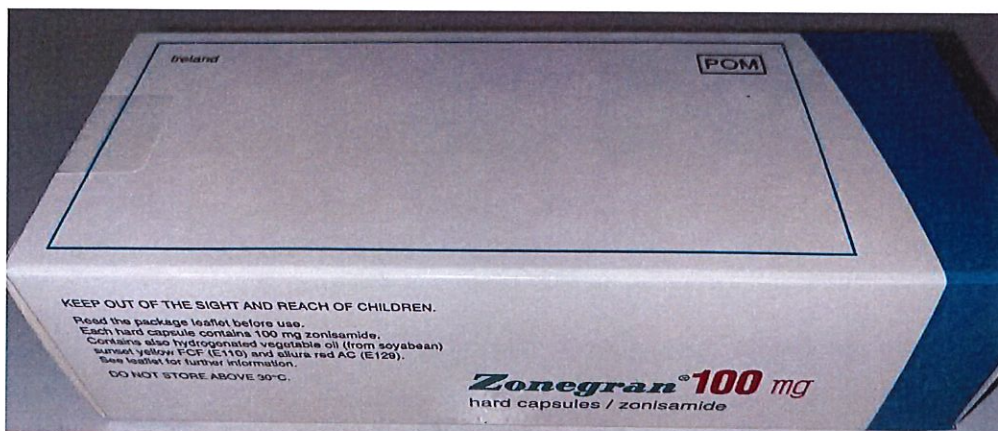
25mg



50mg



100mg



Call for reporting

Advanz Pharma Services (UK) Limited / Capital House / 85 King William Street / London / EC4N 7BL / United Kingdom  
T: +44 (0) 208 588 9100 / F: +44 (0) 208 588 9200 E: [enquiries@advanzpharma.com](mailto:enquiries@advanzpharma.com) / [www.advanzpharma.com](http://www.advanzpharma.com)

Company No 4678629






Healthcare professionals are asked to report any suspected adverse reactions to the Yellow Card Scheme electronically. Report via the website <https://yellowcard.mhra.gov.uk/>, 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 effects 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 timing, treatment dates, and product brand name.

**Company contact point**

If you have any questions about this letter or require more information about Zonegran 25mg/50mg/100mg capsules, please contact Mercury Pharmaceuticals Limited Medical Information at [medicalinformation@advanzpharma.com](mailto:medicalinformation@advanzpharma.com) or +44 (0) 208 588 9131.

Yours faithfully,



25 Oct 2022

Asif Muhammad  
Head of Quality and Responsible Person  
Mercury Pharmaceuticals Limited

