

Date: 28<sup>th</sup> July 2022

## DIRECT HEALTHCARE PROFESSIONAL COMMUNICATION

### **Ponvory (ponesimod) 20 mg film-coated tablets (maintenance pack): Interim Supply of Irish Stock to Mitigate Supply Disruption**

Dear Healthcare Professional,

**Summary: Janssen-Cilag is currently experiencing supply disruption with Ponvory (ponesimod) 20 mg film-coated tablets (maintenance pack).**

To ensure continuity in supply, Janssen-Cilag has obtained approval from the Medicines and Healthcare products Regulatory Agency (MHRA) to supply Irish product (batch numbers KP0060, KP0052, KP0081, KP0102, KP0124 and KP0061) which is expected to be on the Great Britain market from the last week of July 2022 to the 2<sup>nd</sup> week of September 2022.

Please note the following:

- This product is considered licensed in the UK.
- The product from Ireland has the same formulation as the Great Britain product.
- The product from Ireland is manufactured according to the same manufacturing process and quality controls as the Great Britain product.
- The Irish product contains English and Greek language, as these packs are also used in Malta and Cyprus.
- There are no differences between the Irish and UK product information. Please ensure that patients follow the leaflet provided with the pack. Side effects can be reported using the details provided for United Kingdom (Northern Ireland).
- 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 Ponvory and that the information must be given in English.

Please ensure all relevant staff are made aware of the content of this letter, including any hospital pharmacists that place direct orders, 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 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 Ponvory, please contact the Janssen Medical Information Department via email at [medinfo@its.jnj.com](mailto:medinfo@its.jnj.com) or by telephone on 0800 731 8450.

Yours faithfully,

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