

Date: 15 June 2021

DIRECT HEALTHCARE PROFESSIONAL COMMUNICATION

**Xaluprine 20mg/ml oral suspension (mercaptopurine monohydrate)
Interim Supply of Ireland Stock to Mitigate Supply Disruption**

Dear Healthcare Professional,

Summary: Nova Laboratories Limited is currently experiencing supply disruption with Xaluprine 20mg/ml oral suspension (mercaptopurine monohydrate) in the UK (Northern Ireland).

To ensure continuity of supply to the UK (Northern Ireland) market Nova Laboratories Limited has obtained approval from the MHRA to supply product intended for Ireland (batch number 1230Pj101; batch size 85 packs). This product is expected to be on the UK(Northern Ireland) market from June 2021 to December 2021.

Please note the following:

- The product from Ireland has the same formulation as the UK product
- The product from Ireland is manufactured according to the same manufacturing process and quality controls as the UK product.
- There are minor differences between the Irish and UK product information. Key differences are in the reporting of side effects information in the Irish PIL 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 the Irish packs. Discard the Irish 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 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 Xaluprine.

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, SystemOne, 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 Xaluprine 20mg /ml Oral suspension, please contact Nova Laboratories Limited Medical Information at Martin House, Gloucester Crescent, Wigston, Leicester, LE18 4YL or telephone 0116 223 0100 or www.novalabs.co.uk

Yours sincerely



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