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Berkshire
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United Kingdom

Medical Information: 0800 008 7401

August 2024

DIRECT HEALTHCARE PROFESSIONAL COMMUNICATION

Fampyra 10mg Prolonged Release Tablets (fampiridine):
Interim Supply of Belgium Stock to Mitigate Supply Disruption

Dear Healthcare Professional,

Summary: Biogen is currently experiencing supply disruption with Fampyra 10mg Prolonged Release Tablets (fampiridine) in the UK (Great Britain).

To ensure continuity in supply, Biogen has obtained approval from the MHRA to supply Belgium product (batch number 122148; batch size (approx. 3270 packs) which is expected to be on the UK (Great Britain) market from October to December 2024.

Please note the following:

- This product is considered licensed in the UK.
- The product from Belgium has the same formulation as the UK (Great Britain) product
- The product from Belgium is manufactured according to the same manufacturing process and quality controls as the UK (Great Britain) product.
- There are minor differences between the Belgium 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 the Belgium packs. Discard the Belgium leaflet in the pack.
- For additional copies of the leaflet, please refer to https://www.medicines.org.uk/emc/product/4763/pil#about-medicine or contact the company contact point (see below).
- 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 Fampyra 10mg Prolonged Release Tablets 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.

Call for reporting
Please continue to report suspected adverse drug reactions (ADRs) to the MHRA through the Yellow Card scheme.

Please report:

- all suspected ADRs that are serious or result in harm. Serious reactions are those that are fatal, life-threatening, disabling or incapacitating, those that cause a congenital abnormality or result in hospitalisation, and those that are considered medically significant for any other reason.

You can report via:

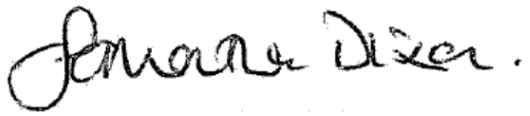
- the Yellow Card website
- the free Yellow Card app available from the Apple App Store or Google Play Store
- some clinical IT systems (EMIS/SystmOne/Vision/MiDatabank) for healthcare professionals

Alternatively, you can report a suspected side effect to the Yellow Card scheme by calling 0800 731 6789 for free, Monday to Friday between 9am and 5pm.

When reporting please provide as much information as possible, including information about medical history, any concomitant medication, timing onset, treatment dates, and product brand name.

Company contact point
If you have any questions about this letter or require more information about **Fampyra 10mg Prolonged Release Tablets**, please contact Biogen Medical Information on 0800 008 7401 or MedInfoUKI@biogen.com.

Yours faithfully,



Dr Samantha Dixon
Head of Medical, UK and Ireland
Biogen Idec Limited