Johnson&Johnson

Date: 15th December 2024

DIRECT HEALTHCARE PROFESSIONAL COMMUNICATION

Concerta XL 27 mg prolonged-release tablets (methylphenidate hydrochloride):

Interim Supply of Finnish and Norwegian Stock to Mitigate Supply Disruption

Dear Healthcare Professional,

Summary: Janssen-Cilag Ltd (a Johnson & Johnson Company) is currently experiencing supply disruption in the UK with: Concerta XL 27 mg prolonged-release tablets (methylphenidate hydrochloride)

To ensure continuity in supply, Janssen-Cilag Ltd (a Johnson & Johnson Company) has obtained approval from the MHRA to supply:

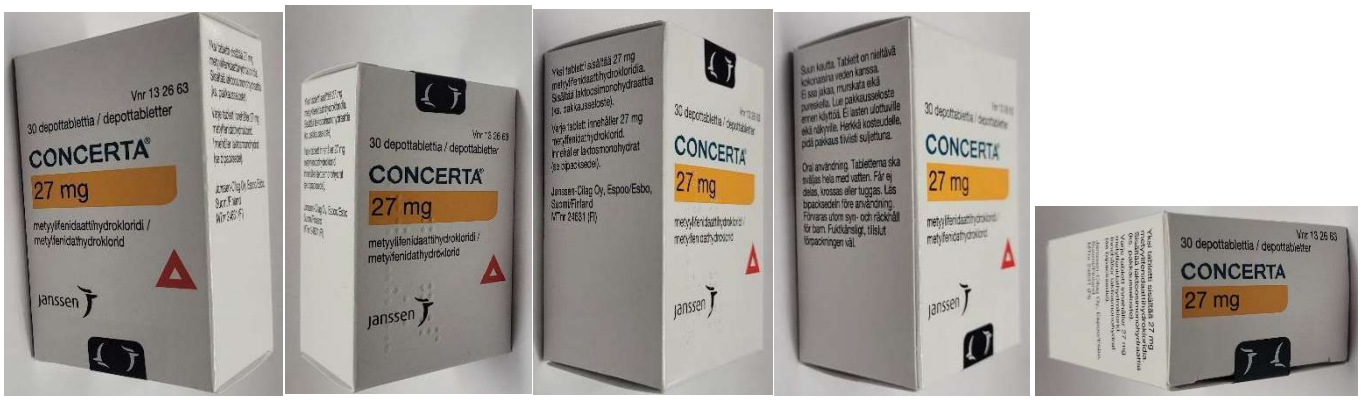
- **Finnish product – Concerta 27 mg: batch number 24NG429X; batch size 11400 units** which is expected to be on the UK market from 15th December 2024 to 15th March 2025,
- **Norwegian product – Concerta 27 mg: batch number 2118954; batch size 19752 units,** which is expected to be on the UK market from 15th December 2024 to 15th March 2025.

Please note the following:

- This product is considered licensed in the UK.
- The products from Finland and Norway have the same formulation as the UK product.
- The products from Finland and Norway are manufactured according to the same manufacturing process and quality controls as the UK product.
- There are minor differences between the Finnish/Norwegian and UK product information. Key differences are in point 4.7 "Effects on ability to drive and use machine" of the UK SPC (contains more 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 each of the Finnish and Norwegian packs. Discard the Finnish/Norwegian leaflet in the pack and supply the UK approved PIL when dispensing to a patient.
- For additional copies of the PIL, please refer to https://www.medicines.org.uk/emc/files/pil.314.pdf 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 (Great Britain), from the obligation that certain particulars should appear on the outer and immediate packaging of Finland and Norway 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.

FINNISH PACK:



Janssen-Cilag Limited, a Johnson & Johnson Company

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tel 01494 567567 fax 01494 567568

Janssen.com/UK/johnson-johnson-innovative-medicine
Registered in England 1027904

NORWEGIAN PACK:

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 Concerta XL, please contact Janssen-Cilag Ltd (a Johnson & Johnson Company) Medical Information via e-mail at: medinfo@its.jnj.com
or telephone 0800 731 8450 or 01494 567 444.

Yours faithfully,

John D Fleming

John Fleming
Medical Director UK
Janssen-Cilag Ltd (a Johnson & Johnson Company)

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