D R U G A L E R T

CLASS 2 MEDICINES RECALL

Action Within 48 Hours
Community Pharmacy and Wholesaler Level Recall

Date: 03 September 2014 EL (14)A/14 Our Ref: MDR 49-08/14

Dear Healthcare Professional,

McNeil Products Limited

Domperidone

Product Name	Pharmaceutical Form	Pack Size	Licence Number	Legal Status
Motilium 10	10mg Tablets	1 x 10	PL 15513/0347	P
Motilium Instants	10mg Orodispersible Tablets	1 x 10	PL 15513/0350	P

Johnson & Johnson Ltd., on behalf of the Marketing Authorisation Holder McNeil Products Limited, is recalling all unexpired stock of the above products. This follows a Europe-wide review of the safety and efficacy of all domperidone products which has resulted in the conclusion by the UK Commission on Human Medicines (CHM) that products containing domperidone no longer meet the requirements for supply with legal status 'P' (i.e. in a pharmacy without prescription, under the supervision of a pharmacist).

Remaining stocks of the above products should be quarantined.

Pharmacists and wholesalers will be contacted directly by Johnson and Johnson Ltd. with details of the returns process. Please wait for instructions from Johnson and Johnson Ltd. before returning any stock. If you have stock of the above products and have not heard from the company within 10 days of the date on this Drug Alert or if you have returns enquiries after reading the instructions please contact Johnson and Johnson Ltd. Pharmacy Sales Support on 0808 238 978

For medical information enquiries please contact Johnson and Johnson Ltd. Professional Information on 01748 828800

Please note domperidone products with legal status POM are not included in the scope of this recall.

Advice to Pharmacists
Domperidone containing products must not be sold to anyone without a prescription. This medicine is associated with a small increased risk of serious cardiac effects, hence patients need to have a medical assessment before taking domperidone to determine whether it is suitable for them (please see further details in the appendix).

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Recipients of this Drug Alert should bring it to the attention of relevant contacts by copy of this letter. Local area teams are asked to forward this to community pharmacists.

Yours faithfully

Alison Bunce

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Your ref: 12345A
My ref: EL (14)A/14

03 September 2014

Dear Healthcare Professional

Domperidone: now only available as a Prescription Only Medicine (POM) from 4th September

Summary

Medicines containing domperidone are only available on prescription from the 4th September.

Domperidone is associated with a small increased risk of serious cardiac side effects. The UK Commission on Human Medicines (CHM) has concluded that products containing domperidone meet the requirements for prescription-only supply. Therefore people need to have a medical assessment before taking domperidone to determine if it is suitable for them.

Background

A Europe-wide review concluded earlier this year that the indication for domperidone should be restricted to use in the relief of nausea and vomiting. New contraindications and changes in posology were also introduced following evidence of a small increased risk of serious cardiac side effects (eg, QTc prolongation, torsade de pointes, serious ventricular arrhythmia, and sudden cardiac death). The MHRA communicated the new recommendations to healthcare professionals on 25th April 2014.

The European review recommended that medical intervention is likely to be needed to identify patients suitable for treatment with domperidone. Taking account of the new recommendations, contraindications and warnings now in place to minimise the small risk of serious cardiac effects, the CHM concluded that domperidone is no longer suitable for supply without prescription.

Advice for healthcare professionals

- Domperidone must not be sold without prescription
- Non-prescription domperidone products (Motilium 10 and Motilium instants) are being recalled
- The updated prescription advice should be taken into consideration before prescribing domperidone (see MHRA Drug Safety Update article from May 2014: http://www.mhra.gov.uk/Safetyinformation/DrugSafetyUpdate/CON418518)

Advice to give to patients

- If you have recently bought domperidone without a prescription and you wish to continue taking it, speak to your doctor or pharmacist at your next routine visit. There is no problem if you wish to stop and a healthcare professional can advise on suitable alternatives for nausea and vomiting.
- If you have been prescribed domperidone, there is no need to stop taking it. Speak to your doctor or pharmacist at your next routine visit if you have any heart problems or other concerns about the treatment.
- Talk to a doctor straight away if you experience dizziness; fainting; chest pain; or a rapid, fluttering, or pounding heartbeat while taking domperidone.

Reporting side effects

Please report any suspected side effects to any medicine or vaccine to the Yellow Card Scheme via the website (www.mhra.gov.uk/yellowcard) or by calling the free phone line (0800 731 6789). By reporting side effects you can help provide more information on the safety of medicines.

Yours sincerely,

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