# Guidance on the Safe Supply of Non-Prescription Medicinal Products Containing Domperidone

Pharmaceutical Society of Ireland

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## Contents

# 1. Introduction

The purpose of this guidance is to ensure pharmacists supply non-prescription medicines containing domperidone safely and in line with the updated product information for these products, following the European Medicines Agency (EMA) review of their use.

An evaluation of the benefits and risks of domperidone was undertaken by the EMA, due to concerns regarding cardiac adverse effects associated with domperidone use. The results were published in April 2014 and found that people who take the drug may have an increased risk of serious cardiac adverse drug reactions. A higher risk was observed in patients over 60 years old, adults taking daily oral doses of more than 30mg and those concomitantly taking QT-prolonging medicines or CYP3A4 inhibitors.

In order to mitigate the risk of cardiac adverse drug reactions new recommendations regarding the supply of domperidone were issued by the EMA. These recommendations were endorsed by the European Commission in September 2014 and are now legally binding. The relevant Summaries of Product Characteristics (SmPCs) and Package Leaflets are being updated to reflect these new recommendations and will be available to view at www.hpra.ie.

In light of the EMA review, a number of European countries, including the UK, have re-classified all domperidone containing products to Prescription Only Medicines (POM). Whilst domperidone is still available without a prescription from pharmacies in Ireland, it requires additional monitoring and as a result of the potential safety concerns, only the pharmacist should supply non-prescription domperidone to patients. Any suspected adverse reactions related to the use of domperidone must be reported immediately to the Health Products Regulatory Authority (HPRA).

# 2. Guidance

The PSI would like to highlight the following key points that must be adhered to in the supply of non-prescription medicinal products containing domperidone from a retail pharmacy business.

## 2.1 Therapeutic Indication and Dose

- Domperidone is ONLY indicated for the relief of nausea and vomiting in adults and adolescents 12 years of age and older, and weighing 35kg or more (NB domperidone is no longer authorised to treat other conditions such as bloating or heartburn).
- The recommended dose of domperidone in adults and adolescents ≥ 35 kg is 10 mg orally up to three times daily with a maximum dose of 30 mg per day.
- Domperidone should be recommended at the lowest effective dose for the shortest possible period, which should not usually exceed one week.

## 2.2 New Contraindications

Domperidone is now contraindicated in the following situations:

- Patients who have a condition where cardiac conduction is, or could be, impaired
- Patients with underlying cardiac disease, such as congestive heart failure
- Co-administration with QT prolonging medicines
- Co-administration with potent CYP3A4 inhibitors
- Patients with severe hepatic impairment

# 3. Pharmacovigilance

Due to these safety concerns Domperidone is subject to additional monitoring to allow continued assessment of the benefit/risk balance of this medicine. A black inverted triangle will appear on the Package Leaflet and in the Summary of Product Characteristics (SmPC) along with a short explanatory sentence to alert patients and healthcare professionals that this medicine is subject to additional monitoring. The black triangle is a visual prompt to alert healthcare professionals and patients to report any suspected adverse reactions associated with the use of domperidone.

Any suspected adverse reactions should be reported to the HPRA using the online Human Medicines Adverse Reaction Report system at www.hpra.ie, by telephone: +353 1 676 4971, by email: medsafety@hpra.ie or by obtaining a Yellow Card from the HPRA and returning it to: Pharmacovigilance, Health Products Regulatory Authority, Kevin O'Malley House, Earlsfort Centre, Earlsfort Terrace, Dublin 2.

# 4. Key Responsibilities for Pharmacists

The supply of non-prescription domperidone containing medicines should only be carried out by the pharmacist. The pharmacist should carry out a thorough consultation with each patient to determine if it is safe and appropriate to make the supply.

Appropriate counselling and advice should be provided to the patient by the pharmacist in order to ensure the correct use of these products in line with the updated product information. Patients should be advised to consult their doctor or pharmacist immediately if signs or symptoms occur that may be associated with cardiac arrhythmia. Patients should also be advised to report any cardiac symptoms while taking domperidone to the pharmacist or directly to the HPRA using the contact information provided above.

In situations where a pharmacist deems the supply to be unsafe or inappropriate, they should clearly explain the reasons to the patient, and facilitate the patient with an alternative treatment or referral to a medical practitioner for further assessment.

# 5. Storage and Promotion of Domperidone Containing Medicines

Due to the safety precautions that must be exercised, and the requirement for the pharmacist to be directly involved in the decision to supply this medicine, non-prescription domperidone containing medicines should not be accessible to the public for self-selection and should be stored in the dispensary under the direct control and supervision of the pharmacist.

# 6. Policies and Procedures

Superintendent and supervising pharmacists must review all pharmacy policies and procedures to ensure that they are in line with this guidance and ensure all pharmacists and staff members are trained on, and operating in compliance with, these policies and procedures.

As stated above, the safety situation around these medicines will be subject to ongoing monitoring, and the PSI, in co-operation with the HPRA, will continue to keep pharmacists informed of any further developments or advice in relation to these products.

# 7. Further Reading

European Medicines Agency confirms recommendations on restricting use of domperidone-containing medicines; European Medicines Agency, 25/4/2014

Domperidone-containing medicines: risk of cardiac adverse reactions-restricted indication, new contraindications and reduced dose and duration of use; Irish Medicines Board Drug Safety Newsletter, 61st Edition, May 2014

Restrictions on use of domperidone-containing medicines; National Medicines Information Centre, Therapeutics Today, Number 5, May 2014

| Version Number | Date Issued |
|---|---|
| 1 | November 2011 |
| 2 | October 2014 |

# 8. Self-assessment Checklist

This self-assessment checklist is a practical tool intended to aid compliance with this guidance and to assist superintendent and supervising pharmacists in drawing up the relevant policies and SOPs. The checklist captures many important elements of the guidance; it is not exhaustive and should only be used to assess pharmacy practice in combination with this guidance and all other relevant guidance and requirements.

| Ask Yourself | Yes | No | N/A | Required Action |
|---|---|---|---|---|
| Are the pharmacist and all relevant staff members aware of the new recommendations regarding the supply of medicinal products containing domperidone? | | | | |
| Are all members of staff aware that all requests for domperidone must be referred to the pharmacist? | | | | |
| Is the pharmacist aware of the new licensed indications and contraindications for domperidone? | | | | |
| Does the pharmacist carry out a thorough consultation with each patient to determine if domperidone is safe and suitable for them to use? | | | | |
| Does the pharmacist counsel the patient to ensure that they are clear on the new recommended dose and safe use of domperidone? | | | | |
| Is the pharmacist aware that domperidone is subject to additional monitoring, and that any suspected adverse reactions should be reported to the HPRA? | | | | |
| Are all non-prescription products containing domperidone stored in the dispensary under the direct control and supervision of the pharmacist? | | | | |
| Are there written policies and procedures in place for all aspects of the supply of domperidone? | | | | |
| Is the superintendent pharmacist and supervising pharmacist satisfied that all pharmacists practising in the pharmacy, and relevant staff members, are trained on, and following, the policies and procedures? | | | | |