



DRUG REGULATORY AUTHORITY OF PAKISTAN  
MINISTRY OF NATIONAL HEALTH SERVICES, REGULATIONS & COORDINATION  
PAKISTAN NATIONAL PHARMACOVIGILANCE CENTRE (PNPC)  
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Islamabad, the 17<sup>th</sup> October, 2019.

### SAFETY ALERT OF RISK OF SERIOUS CARDIAC ADVERSE EVENTS ASSOCIATED WITH DOMPERIDONE IN CHILDREN UNDER 12 YEARS OF AGE.

The European Medicines Agency (EMA) and the Agency for the Safety of Medicines and Health Products (ANSM), France confirmed the risk of serious cardiac adverse events associated with the use of domperidone including QT prolongation, Torsade De Pointes, Serious Ventricular Arrhythmias and Sudden Cardiac Death. As part of the re-evaluation of the benefit-risk balance of domperidone conducted by the European Medicines Agency (EMA) in 2014, an efficacy study for children under 12 years of age was requested. The results of this study, presented this year, showed no difference in efficacy compared to placebo. Because of this lack of efficacy and its undesirable effects, the use of domperidone is therefore restricted to adults and adolescents over 12 years old and weighing more than 35kg. Domperidone is not currently a legally marketed human drug in USA and is not approved for sale.

Based on the above new update, the case was presented in 290<sup>th</sup> meeting of Registration Board, which after deliberation decided that manufacturers/ importers of domperidone containing drugs should updated the prescribing information and patient information as per the recommendation by EMA.

#### **INFORMATION FOR HEALTHCARE PROFESSIONALS**

- ✓ Domperidone should only be used for the relief of nausea and vomiting symptoms.
- ✓ The dose is limited to 10 mg up to 3 times daily, with a maximum dose of 30 mg per day.
- ✓ The duration of treatment should be as short as possible
- ✓ Medications based on domperidone are contraindicated especially in cases of hepatic insufficiency and in certain situations at risk of prolongation of QT (cardiac pathologies, drug interactions).
- ✓ The use of domperidone should be restricted to adults and adolescents over 12 years of age and weighing more than 35kg.
- ✓ The indication in children has been discontinued due the unfavorable benefit/risk ration.
- ✓ If any patient experience the above mentioned adverse events or any other event, it should be reported to DRAP through:  
<https://www.dra.gov.pk/docs/Suspected%20Adverse%20Reaction%20Reporting%20Form%20for%20Health%20Care%20Professionals.pdf>

#### **INFORMATION FOR PATIENTS/RELATIVE OF PATIENTS.**

- ✓ If your child is below the age of 12 years or 35kg, you must stop the use of domperidone and consult the doctor.
- ✓ If you are a patient and experience adverse events with use of domperidone such as abnormal heart beat or any other heart related problems, immediately consult your physician and ask him/her to report the adverse drug reaction to Pakistan National Pharmacovigilance Centre, DRAP.