

# **Domperidone and risk of QTc prolongation, serious ventricular arrhythmias and sudden cardiac death**

**Final SmPC and PL wording agreed by PhVWP in October 2011**

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## **SUMMARY OF PRODUCT CHARACTERISTICS**

### **Section 4.2**

A cross reference should be proposed to section 4.4 in section 4.2.  
See section 4.4

### **Section 4.4**

Cardiovascular effects:

Some epidemiological studies showed that domperidone may be associated with an increased risk of serious ventricular arrhythmias or sudden cardiac death (see section 4.8.) The risk may be higher in patients older than 60 years or at daily doses of more than 30 mg. Domperidone should be used at the lowest effective dose in adults and children.

Use of Domperidone and other drugs which prolong QTc intervals requires that caution be exercised in patients who have existing prolongation of cardiac conduction intervals, particularly QTc, patients with significant electrolyte disturbances or underlying cardiac diseases such as congestive heart failure.

### **Section 4.8 Undesirable Effects**

Ventricular arrhythmias and sudden cardiac death should be included under SOC cardiac disorders with frequency 'unknown'. Cross reference should be made to section 4.4.

## **PACKAGE LEAFLET**

### **Additional text in section 2 “Before taking your Medicine” and section 4 “Possible side effects”**

Domperidone may be associated with an increased risk of heart rhythm disorder and cardiac arrest. This risk may be more likely in those over 60 years old or taking doses higher than 30mg per day. Domperidone should be used at the lowest effective dose in adults and children.