



Department of  
**Health, Social Services  
and Public Safety**

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AN ROINN

**Sláinte, Seirbhísí Sóisialta  
agus Sábháilteachta Poiblí**

MÁNNYSTRIE O

**Poustie, Resydènter Heisin  
an Fowk Siccar**

From The Chief Pharmaceutical Officer  
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**For Action:** Assistant Director Pharmacy and Medicines Management  
HSC Board & BSO  
Directors of Pharmaceutical Services of HSC Trusts  
Regional Quality Improvement Authority

Our Ref: PHC/39/09

Date: 18 December 2009

## **DRUG ALERT**

Dear Healthcare Professional

**Teva UK Limited**

**Ondansetron IV Injection 2mg/ml (2ml) and 2mg/ml (4ml) (All supplied in Pliva livery)  
PL 10622/0102**

Teva UK Limited have informed us that they have not complied with regulatory undertakings to update the SPC or patient information leaflet contained in already distributed packs. All stock in the distribution chain is missing some safety information.

We understand that it will be about four months before acceptable stock enters the supply-chain. To avoid stock shortages existing stock is **not** being recalled.

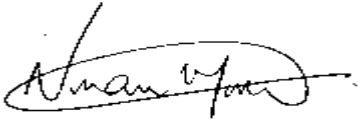
The missing information is listed in the attached annex. Please forward this to relevant physicians.

For medical information enquiries and questions about the patient information leaflet or SPC, please contact Teva UK medical information on 0207 5407717

HSC Board/RQIA should bring this information to the attention of private hospitals/clinics registered with them and any other relevant care facilities.

The Business Services Organisation is asked to bring this information to the attention of Community Pharmacists and General Medical Practitioners directly.

Yours sincerely



**DR NORMAN MORROW**  
Chief Pharmaceutical Officer

For information:

CMO  
CNO  
CDO  
CISSI  
SMO  
Director, Health Estates  
Public Health Branch  
DHSSPS, Library  
Extended nurse prescribers

Regional Medicines and Poisons Information Service  
Regional Director of Supplies  
RPLS  
Pharmaceutical Society of NI  
Senior Prison Pharmacist  
Prison Service, Dundonald House  
Nursing Officer, Health Estates  
Medical Officer, Castle Buildings  
Regional Procurement Pharmacist  
NICPLD

## **Annex**

**Ondansetron IV Injection 2mg/ml (2ml) and 2mg/ml (4ml) supplied by Teva UK Ltd has the following information omitted:-**

**The SPC leaflet dated 05/2007 does not have these paragraphs in the relevant sections.**

### 4.4 Special warnings and precautions for use

Very rarely and predominately with intravenous ondanestron transient ECG changes including QT interval prolongation have been reported. Therefore caution should be exercised in patients with cardiac rhythm or conduction disturbances, in patients treated with anti-arrhythmic agents or beta-adrenergic blocking agents and in patients with significant electrolyte disturbance.”

### 4.5 Interaction with other medicinal products and other forms of interaction

Ondanestron is metabolised by multiple hepatic cytochrome P450 enzymes: CYP3A4, CYP2D6, CYP1A2. Due to the multiplicity of metabolic enzymes capable of metabolising ondansetron, enzyme inhibition or reduced activity of one enzyme (e.g CYP2D6 genetic deficiency) is normally compensated by other enzymes and should result in little or no significant change in overall ondansetron clearance or dose requirement.

**The Patient Information Leaflet dated 05/2007 does not include the second sentence regarding symptoms of overdose.**

**“If you receive more Ondansetron than you should** Ondanestron injections will be given to you by a doctor or nurse, so if you think that you may have had too much, let them know. Symptoms of overdose include visual disturbances, severe constipation, light-headedness, dizziness, fainting.”