

August 2012

Direct Healthcare Professional Communication on new concentration and dosing instructions of TAMIFLU® oral suspension (oseltamivir phosphate)

Dear Healthcare Professional,

Roche Products Limited would like to bring to your attention the following information to help to reduce the potential for prescribing and dosing errors of TAMIFLU® oral suspension. The information provided in this letter has been reviewed and endorsed by the EMA and Medicines and Healthcare products Regulatory Agency (MHRA).

Summary:

- Concentration of TAMIFLU® for Oral Suspension will be changed from 12 mg/ml to **6 mg/ml**
- The dispenser will be changed from milligrams (mgs) to **millilitres (mLs)**
- The EU SPCs will be changed to include amended dosing tables to include a column for the volume in millilitres based on the new 6 mg/ml formulation.

Prescriptions for Tamiflu® oral suspension should state the dose in millilitres and the new 6 mg/ml concentration should be used when available. The patients and parents/guardians of children should be carefully advised that the carton packaging, dosing dispenser and packaging leaflet of the new oral suspension are different from what they may have used in the past.

Please note that the longest dated stock of the current presentation TAMIFLU® 12 mg/ml in the UK expires end July 2012 and there are no later-dated packs available. Therefore between end July and early October 2012 there will be no Tamiflu Suspension presentations available in the UK, until the new presentation (TAMIFLU® for Oral Suspension 6 mg/ml) is introduced. Pharmacies are advised to remove expired stock from shelves in the usual way and to re-order TAMIFLU® for Oral Suspension 6 mg/ml from wholesalers AAH Pharmaceuticals Ltd, Alliance Healthcare Ltd or Movianto Northern Ireland from September 2012.

In the intervening period, please be aware that Tamiflu Capsules are available and we would kindly direct you to the Electronic Medicines Compendium (<http://www.medicines.org.uk/emc/>) for the up to date SPCs, in particular sections "4.2 Posology and method of administration and 6.6 Special

Roche Products Limited

Hexagon Place
6 Falcon Way, Shire Park
Welwyn Garden City
Herts AL7 1TW
Reg in England No 100674

Medical Information

Tel. 0800 3281629
Fax 01707 384555

precautions for disposal and other handling”, which describe the preparation of suitable dosage forms, when powder for oral suspension is unavailable.

Tamiflu is indicated for treatment of influenza in patients one year of age and older who present with symptoms typical of influenza, when influenza virus is circulating in the community within two days of first onset of symptoms. It is also indicated for post-exposure prevention in individuals one year of age or older following contact with a clinically diagnosed influenza case when influenza virus is circulating in the community.

During a pandemic influenza outbreak Tamiflu is also indicated for the treatment and post-exposure prevention of influenza in infants below 12 months of age.

Call for reporting:

Please be reminded that suspected adverse reactions associated with the use of Tamiflu should be reported through the Yellow Card Scheme online at www.mhra.gov.uk/yellowcard

Alternatively, prepaid Yellow Cards for reporting are available:

- Upon request by mail “FREEPOST YELLOW CARD”
- At the back of the British National Formulary (BNF)
- By telephoning the Commission on Human Medicines (CHM) free phone line: 0800-731-6789
- Or by electronic download through the MHRA website (<http://yellowcard.mhra.gov.uk/downloads/>)

When reporting please provide as much information as possible including, information about medical history, any concomitant medication, onset and treatment dates.

Healthcare professionals may also report any adverse events suspected to be associated with the use of Tamiflu to Roche by phone on 01707 367554, by fax on 01707 367582 or e-mail at welwyn.uk_dsc@roche.com

Should you have any questions or require additional information regarding the use of oseltamivir phosphate, please contact: Roche Medical Information by phone on 0800 3281629 or by email on Medinfo.uk@roche.com.

Yours sincerely,



Michelle Rashford
Medical Director
Roche Products Limited

The Tamiflu 6mg/ml Powder for Oral Suspension Summary of Product Characteristics is available via the Electronic Medicines Compendium at <http://www.medicines.org.uk/emc>