18th October 2012

Direct Healthcare Professional Communication on new concentration and dosing instructions for TAMIFLU® powder for oral suspension

Dear Healthcare Professional,

Roche Products (Ireland) 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 European Medicines Agency and the Irish Medicines Board.

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 Summary of Product Characteristics (SmPC) 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 find enclosed a copy of the following for your reference:

- Tamiflu 6mg/ml Powder for Oral Suspension SmPC (Version dated 10-September2012)
- Tamiflu 6mg/ml Powder for Oral Suspension Package Leaflet (Version dated September 2012)

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.

For full details of the indications for Tamiflu 6mg/ml powder for oral suspension, please refer to section 4.1 of the enclosed SmPC.

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Call for reporting:

Healthcare professionals are reminded to continue to report any suspected adverse events occurring with the use of Tamiflu to the Drug Surveillance Centre at Roche Products (Ireland) Limited (either by mail, telephone [01 4690700], fax [01 4690793] or e-mail [Ireland.drug_surveillance_centre@roche.com]). Alternatively, suspected adverse events may be reported to the pharmacovigilance section of the Irish Medicines Board in the usual manner.

In addition, a web-based online entry form for consumer and healthcare professionals for reporting of oseltamivir-related adverse events/reactions is available.

This online tool was created to ensure that safety data is continuously forwarded to the MAH, including during future pandemics when the AE reporting rate from healthcare professionals may fall due to increasing work load.

Access to ePRT- electronic Pandemic Reporting Tool can be accessed via
http://www.roche.com/index.htm
then click on Products -> Pharmaceuticals to reach this web address:
http://www.roche.com/products/product-list.htm?type=divpharma&id=Pharmaceuticals

Products are displayed in alphabetical order:

click on 'Tamiflu'

subwindow expands with the link at the right:

"Report side effects on Tamiflu"

Should you have any questions or require further information regarding the use of Tamiflu, please contact Medical Information at Roche (by mail, telephone [01 4690700], fax [01 4690791] or e-mail [ireland.druginfo@roche.com]).

Yours sincerely,

Dr. Mariluz Amador
Medical Director