IMPORTANT PRESCRIBING INFORMATION

Tamiflu® oseltamivir phosphate

treat. prevent. protect.

August 12, 2013

RE: Announcing a new National Drug Code (NDC) for TAMIFLU® (oseltamivir phosphate) 6 mg/mL for Oral Suspension: 0004-0822-05

Dear Pharmacist,

This letter is to inform you that Genentech is implementing a new NDC for TAMIFLU® (oseltamivir phosphate) for Oral Suspension **(NDC 0004-0822-05)**. This coding change was prompted by the company's decision to remove the 10 mL dispenser (syringe and bottle adaptor) from the carton. The drug product remains exactly the same.

What has changed:

- The outside carton has changed
- The 10mL dispenser (syringe and bottle adaptor) has been removed from the carton
- **Pharmacists should ensure patient has an appropriate dosing device**
- There is a new NDC number for TAMIFLU for Oral Suspension
- Text changes have been made to the carton, bottle label and Prescribing Information to reflect the new NDC 0004-0822-05 and to remove references to the oral dispenser

What has not changed:

- The drug product (oseltamivir phosphate) remains the same
- The concentration of TAMIFLU for Oral Suspension (6 mg/mL) has not changed
- The bottle size (60mL) and carton size has not changed
- Standard Return Goods Policy apply

In addition to the December 2012 approval of Tamiflu for treatment of acute, uncomplicated influenza in patients 2 weeks of age and older who have been symptomatic for no more than 2 days, there are now revised compounding and dosing instructions. For all dosing instructions please refer to the Package Insert.

Safety and efficacy have not been established for prophylaxis of influenza in pediatric patients less than 1 year of age and have not been established for treatment of influenza in pediatric patients less than 2 weeks of age.

The safety profile observed in pediatric patients 2 weeks to less than 1 year of age was consistent with the established safety profile of subjects aged 1 year and above, with vomiting, diarrhea and diaper rash being the most frequently reported adverse reactions

The important safety information in this letter is not comprehensive. Please refer to the full prescribing information accompanying this letter, which can be downloaded at:
http://www.gene.com/gene/products/information/tamiflu/pdf/pi.pdf.

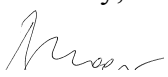
For more information about TAMIFLU® (oseltamivir phosphate), please visit us at http://www.tamiflu.com/hcp.

For medical information questions regarding TAMIFLU, please contact Genentech Medical Communications at 1-800-821-8590 (5:30 a.m.-4 p.m. PST, M-F).

Adverse reactions or quality problems experienced with the use of this product may be reported to the FDA's MedWatch Adverse Event Reporting program either online, by regular mail, telephone, or fax.

- Online : www.fda.gov/medwatch
- Regular Mail : use postage-paid, pre-addressed Form FDA 3500 available at: www.fda.gov/MedWatch/getforms.htm . Mail to: MedWatch, 5600 Fishers Lane, Rockville, MD 20857
- Telephone : 1-800-332-1088
- Fax : 1-800-FDA-0178

Sincerely,



Bruce Cooper
Head, U.S. Medical Affairs
Genentech, Inc.