

DOSING AND ADMINISTRATION UPDATE

Information for medical practitioners

9 June 2009

Tamiflu® (oseltamivir) 30mg, 45mg & 75mg capsules available Extemporaneous preparation outline

Despite a shortage of Tamiflu suspension, Roche has a limited supply of Tamiflu 30mg and 45mg capsules to treat paediatric patients over 1 year of age presenting with influenza.

General Practitioners continue to be able to prescribe 30mg and 45mg capsules for patients presenting with influenza. Community pharmacists will be able to fulfil these prescriptions by ordering capsules directly from Roche by following the ordering protocol issued on 2 June 2009 to community pharmacists and GPs (see below).

Roche continues to have sufficient commercial supply of Tamiflu 75mg capsules and this strength continues to be available to community pharmacies via wholesalers.

The Therapeutic Goods Administration (TGA) has approved the preparation of extemporaneous formulations from 30mg, 45mg and 75mg Tamiflu capsules.

This means that adults, adolescents and children (1 year and older) who are unable to swallow capsules can now have powder from Tamiflu capsules mixed with sweetened food products.

Instructions for extemporaneous preparation of Tamiflu capsules are given below and will be included in an updated Product Information.

1. Hold the TAMIFLU capsule(s), corresponding to the required dose, over a small bowl. Carefully pull the capsule(s) open and pour the powder into the bowl,
2. Add a suitable, small amount (1 teaspoon maximum) of sweetened food product such as regular or sugar-free chocolate syrup, honey, light brown or table sugar dissolved in water, dessert toppings, sweetened condensed milk, apple sauce or yogurt to mask the bitter taste of the medication.
3. Stir the mixture well and give the entire contents to the patient. The mixture must be swallowed immediately after its preparation. If there is some mixture left inside the bowl, rinse the bowl with a small amount of water and have the patient drink this remaining mixture. It is not necessary to administer any undissolved white powder as this is inert material.



If the patient requires a dose of TAMIFLU, which is different to that available in capsule form, they may receive their appropriate dose of TAMIFLU by following the instructions below.

1. Hold one TAMIFLU 75 mg capsule over a small bowl. Carefully pull the capsule open and pour the powder into the bowl.
2. Using a graduated syringe, add 5 mL water to the powder. Stir for about two minutes.
3. Draw up into the syringe the correct amount of mixture from the bowl (see table below). The recommended dose is body weight dependent (see Minimum Product Information below). Push down on the plunger of the syringe, to empty its entire contents into a second bowl. Discard any unused mixture.

Recommended dose	Amount of TAMIFLU mixture for one dose
30 mg	2 mL
45 mg	3 mL
60 mg	4 mL

4. In the second bowl, add a suitable, small amount (1 teaspoon maximum) of sweetened food product such as regular or sugar-free chocolate syrup, honey (only for children two years or older), light brown or table sugar dissolved in water, dessert toppings, sweetened condensed milk, apple sauce or yogurt to the mixture to mask the bitter taste of the medication.
5. Stir this mixture well and give the entire contents of the second bowl to the patient. This mixture must be swallowed immediately after its preparation. If there is some mixture left inside the bowl, rinse the bowl with a small amount of water and have the patient drink this remaining mixture.



TAMIFLU (oseltamivir) MEDICAL PRACTITIONER (VIA COMMUNITY PHARMACY) SUPPLY PROTOCOL 30mg & 45mg CAPSULES

This protocol will assist you in ensuring your paediatric patients presenting with cases of influenza have ready access to Tamiflu 30mg and 45mg capsules.

This will be the ordering protocol. We will update you if Tamiflu 30mg and 45mg capsules are going to be supplied via pharmaceutical wholesalers.

Medical Practitioners: To ensure access to supplies of Tamiflu 30mg and 45mg capsules for presenting cases of influenza, Medical practitioners will need to write a brief letter, confirming that the patient has a current influenza infection or is a direct contact, to accompany the script for Tamiflu.

The Patient: The patient must take this letter and script to a retail pharmacy.

The Pharmacist: The pharmacist will need to fax the letter, (remove patient information), to Roche Products Pty Limited on **FAX 1800 641 769** and request direct supply of Tamiflu 30mg or 45mg capsules.

If the pharmacy does not have a direct account with Roche then payment can be arranged through Visa or MasterCard only. This can be done over the phone with Roche, **PHONE 1800 800 766**

Tamiflu will be dispatched to the retail pharmacy via overnight courier. This should be available for the patient to pick up the following day*.

*Note that Roche will need to receive orders by midday in order to guarantee next day delivery. Saturday delivery can be arranged at a surcharge.

Enquiries from Health Professionals – Medical Information Service 1800 233 950

Wholesale Stock enquiries – Customer Service 1800 800 766

Media enquiries about Tamiflu can be directed to: Libby Day on 04070 60045

Minimum Product Information

Tamiflu[®] (oseltamivir)

Indications

Treatment of infections due to influenza A and B viruses in adults and children one year and older. Prevention of influenza in adults and children one year and older.

Dosage

Treatment: Adults and adolescents 75 mg twice daily. Paediatric patients: ≤15 kg: 30 mg twice daily; >15-23 kg: 45 mg twice daily; >23-40 kg: 60 mg twice daily; >40 kg: 75 mg twice daily. Duration of treatment is 5 days. Treatment should be initiated within 48 hours of symptom onset.

Prevention: Adults and adolescents 75 mg daily. Paediatric patients: ≤15 kg: 30 mg once daily; >15-23 kg: 45 mg once daily; >23-40 kg: 60 mg once daily; >40 kg: 75 mg once daily. Duration of therapy is 10 days, beginning within two days of exposure.

Contraindications, Precautions and Adverse Events

TAMIFLU is contraindicated in patients with known hypersensitivity to any component of the product. TAMIFLU should not be used in children under 1 year of age as safety and efficacy have not been established. Caution is advised when administering to patients with renal failure and Hereditary Fructose Intolerance. The most common side effects include vomiting, nausea, insomnia, headache, diarrhoea, dizziness and abdominal pain. In children, also epistaxis, ear disorders and conjunctivitis. Rarely, gastrointestinal bleeding, allergic skin reactions and hepatitis. Closely monitor for convulsions and delirium, predominately in children and adolescents (causality not established).*

Please review the complete Product Information before prescribing this medicine. A full copy of the Product Information is available on request from Roche Products Pty Limited.

Roche Products Pty Limited
ABN 70 000 132 865
4-10 Inman Road
Dee Why 2099

Date of Preparation: 4 June 2009.

* Please note change to Product Information.

If you would like to withdraw your consent for inclusion in Roche mailings and market research, or would like to request access to your personal information please write to the Privacy Officer, Roche Products Pty Limited, PO Box 255, DEE WHY NSW 2099