

IMPORTANT MEDICINE SAFETY INFORMATION

11 September 2019

Dear Healthcare Professional

RE: Tamiflu® Oral Suspension (Osetelmavir) Registration number: 18/20.2.8/0078 – Removal of incorrect statement on the Carton and Professional Information (PI) and Patient Information Leaflet (PIL)

In collaboration with the Namibian Medicines Regulatory Council (NMRC), Roche Products (Pty) Ltd would like to inform you that it is in the process of removing the incorrect text from the Tamiflu 6 mg/mL, powder for oral suspension, carton and leaflet (Professional Information including Patient Information Leaflet).

Tamiflu 6 mg/mL Powder for oral suspension is supplied in a 100 mL amber glass bottle. When the powder is reconstituted with 55 mL of water, it contains a retrievable volume of 64,7 mL (~65 mL) of final product.

The carton and PI/PIL have the statement:

When reconstituted with 55 mL of water, each 1 mL contains 6 mg oseltamivir and 0,05 % *m/v* sodium benzoate as preservative.

Total retrievable volume = 64,7 mL equivalent to 10 doses of 60 mg oseltamivir.

The statement “*equivalent to 10 doses of 60 mg oseltamivir*” is incorrect since the dosing in children is weight based. This text will therefore be removed from the carton and PI/PIL. The carton will have the wording “See enclosed package insert for indications and dosage”

We are in the process of updating the packaging materials and PI/PIL.

Roche's Assessment

Roche will continue to supply Tamiflu and distribute it to the market. This is supported by:

- The amount of Tamiflu to be administered to the patient is calculated as a function of the patient's body weight. This calculation is described correctly in the PI/PIL and is independent from the retrievable volume.

Advise to healthcare professionals

- **Healthcare professionals are advised to follow the dosing as per the approved professional information and taking into account the requirement for weight based dosing.**

Healthcare professionals and patients are encouraged to report all suspected adverse effects associated with the use of Tamiflu (Osetelmavir) to:


Company	Contact details
Roche Products (Pty) Ltd	Drug Safety Unit Tel: +27 11 502 5009 Fax: +27 11 268 5748 email: sa_ssa.drugsafety@roche.com
Therapeutics Information and Pharmacovigilance Centre (TIPC)	Tel : +264 61 203 2406 Fax : +264 61 226631 Fax2mail : 0886606781 email: info.TIPC@mhss.gov.na

For further information, please do not hesitate to contact us.

Yours sincerely,



(Dr) Kgothatso Motumi
Management Centre Medical Head



(Dr) Clinton Rambanapasi
Snr Regulatory Affairs Pharmacist