

24 September 2009

Dear Colleague

Dosage of oseltamivir in children under one year of age with swine flu

This letter is to alert you to a change in the dosage regime for oseltamivir in children aged 6 months and over and up to 1 year of age during an influenza pandemic outbreak.

Up to now, the treatment dose for oseltamivir in children aged under 1 year has been 2 mg/kg given twice a day for 5 days. This was based on the international use of oseltamivir, particularly in Japan, and the advice of the Royal College of Paediatrics and Child Health.

Treatment of Children aged 6 months and over and up to 1 year of age

The manufacturers of Tamiflu (oseltamivir), Roche Products Ltd, has been granted a variation to the Market Authorisation for the treatment of children aged 6 months to 12 months during an influenza pandemic. This means that Tamiflu Suspension is now licensed for use in this age group. Pharmacokinetic data indicate that a dosage of 3 mg/kg twice daily in children 6 to 12 months of age provides plasma drug exposures in the majority of patients similar to those shown to be clinically efficacious in children aged one year or older and adults.

The recommended dose for treatment of children 6 to 12 months of age is now 3 mg per kg body weight twice daily for 5 days for treatment.

There are currently two liquid formulations of oseltamivir in use in Scotland, Oseltamivir Oral Solution 15 mg/mL and Oseltamivir 12 mg/mL Suspension (Tamiflu Suspension). The Oseltamivir 15 mg/mL Solution remains an unlicensed product. That said, only a limited supply of the Tamiflu Suspension remains available in the UK. In order to minimise the potential risk of having two formulations available in primary care, Boards are using either one or the other. Boards using Oseltamivir 15 mg/mL Solution have withdrawn stocks of the 12 mg/mL Suspension from primary care.

In order to assist prescribers the current dosage information for this age group based on the 15_[22] mg/mL Oseltamivir Oral Solution is also set out in the table at **Annex One** and for the 12 mg/mL Oseltamivir Suspension (Tamiflu) is set out in the table at **Annex Three**.

Treatment of Children under 6 months of age

Roche Products Ltd have also submitted data to the European Medicines Regulatory Authority on the use of oseltamivir in children aged 0 to 6 months. It is unlikely that

any decision by the regulator about dosage of Tamiflu in this age group will be made before November 2009.

Therefore the treatment dosage in this age group remains the same as at present at 2 mg/kg twice daily.

Further information will be sent to you when the regulatory authority decides on future dosage regime in this age group. Current dosage information for this age group based on the 15mg in 1mL Oseltamivir Oral Solution is also set out in the table at **Annex Two** and for the 12 mg/mL Oseltamivir Suspension (Tamiflu) in the table at **Annex Four**.

Managing the transition

General Practitioners authorising the supply of oseltamivir for children aged 6 months and over and up to 1 year of age and those supplying the product will need to ensure extra care is taken as this change of dosage is implemented. The implementation plan should be overseen and supervised by Directors of Pharmacy, working closely with Directors of Public Health and Medical Directors.

Prophylaxis

The European Committee for Medicinal Products for Human Use found that there was less evidence to support the use of oseltamivir for the prevention of influenza for children under the age of one year. However, in certain situations, where individuals with a serious underlying condition have been in close contact with an infectious case, clinical judgement may be used to offer a course of prophylaxis. Doctors should, however, consider very carefully the benefits and risks of prophylactic antiviral medicine for each child under the age of one, and may wish to take advice from a specialist in the care of young children.

Yours sincerely,

**DR HARRY BURNS
CHIEF MEDICAL OFFICER
ANNEX ONE**

**PROFESSOR BILL SCOTT
CHIEF PHARMACEUTICAL OFFICER**

ANNEX ONE

Dosage chart for oseltamivir solution 15 mg/mL for children 6 months and over and up to one year of age

TREATMENT: 3 mg/kg given twice a day for 5 days		
PROPHYLAXIS 3 mg/kg given once a day for 10 days		
OSELTAMIVIR solution - 15mg in 1 mL (20mL)		
Dose calculation based on weight and dose of 3 mg/kg		
Weight range (kg)	Dose in mL of solution 15 mg/mL	Quantity to be supplied
6.0 – 6.4	1.2	1 x 20 mL
6.5 – 6.9	1.3	1 x 20 mL
7.0 – 7.4	1.4	1 x 20 mL
7.5 – 7.9	1.5	1 x 20 mL
8.0 – 8.4	1.6	1 x 20 mL
8.5 – 8.9	1.7	1 x 20 mL
9.0 – 9.4	1.8	1 x 20 mL
9.5 – 9.9	1.9	2 x 20 mL
10.0 – 10.4	2.0	2 x 20 mL
10.5 – 10.9	2.1	2 x 20 mL
11.0 – 11.4	2.2	2 x 20 mL
11.5 – 11.9	2.3	2 x 20 mL
12.0 – 12.4	2.4	2 x 20 mL

ANNEX TWO

Dosage chart for oseltamivir solution 15 mg/mL for children under 6 months of age

TREATMENT: 2 mg/kg given twice a day for 5 days

PROPHYLAXIS 2 mg/kg given once a day for 10 days

OSELTAMIVIR solution - 15mg in 1 mL (20mL)

Dose calculation based on weight and dose of **2 mg/kg**

Weight range (kg)	Dose in mL of solution 15 mg/mL	Quantity to be supplied
3.0 – 3.6	0.4	1 x 20 mL
3.7 – 4.3	0.5	1 x 20 mL
4.4 – 5.0	0.6	1 x 20 mL
5.1 – 5.7	0.7	1 x 20 mL
5.8 – 6.4	0.8	1 x 20 mL
6.5 – 7.1	0.9	1 x 20 mL
7.2 – 7.8	1.0	1 x 20 mL
7.9 – 8.5	1.1	1 x 20 mL
8.6 – 9.2	1.2	1 x 20 mL
9.3 – 9.9	1.3	1 x 20 mL

ANNEX THREE

Dosage chart for oseltamivir (Tamiflu) suspension 12 mg/mL for children 6 months and over up to one year of age

TREATMENT: 3 mg/kg given twice a day for 5 days	
PROPHYLAXIS: 3 mg/kg given once a day for 10 days	
OSELTAMIVIR (Tamiflu) suspension – 12 mg/mL (75mL)	
Dose calculation based on weight and dose of 3 mg/kg	
Weight range (kg)	Dose in mL of suspension 12 mg/mL
6.0 – 6.3	1.5
6.4 – 6.7	1.6
6.8 – 7.1	1.7
7.2 – 7.5	1.8
7.6 – 7.9	1.9
8.0 - 8.3	2.0
8.4 – 8.7	2.1
8.8 – 9.1	2.2
9.2 – 9.5	2.3
9.6 – 9.9	2.4
10.0 – 10.3	2.5
10.4 – 10.7	2.6
10.8 – 11.1	2.7
11.2 – 11.5	2.8
11.6 – 11.9	2.9
12.0 – 12.3	3.0

ANNEX FOUR

Dosage chart for oseltamivir (Tamiflu) suspension 12 mg/mL for children under 6 months of age

TREATMENT: 2 mg/kg given twice a day for 5 days	
PROPHYLAXIS: 2 mg/kg given once a day for 10 days	
OSELTAMIVIR (Tamiflu) suspension – 12 mg/mL (75mL)	
Dose calculation based on weight and dose of 2 mg/kg	
Weight range (kg)	Dose in mL of suspension 12 mg/mL
3.0 - 3.5	0.5
3.6 - 4.1	0.6
4.2 – 4.7	0.7
4.8 – 5.3	0.8
5.4 – 5.9	0.9
6.0 – 6.5	1.0
6.6 - 7.1	1.1
7.2 – 7.7	1.2
7.8 – 8.3	1.3
8.4 – 8.9	1.4
9.0 - 9.5	1.5