

IMMEDIATE MESSAGE TO:

1. Medical Directors NHS Boards
2. Directors of Public Health
3. Directors of Pharmacy
4. NHS 24
5. Health Protection Scotland (HPS)

URGENT UPDATED ADVICE ON DOSAGE OF OSELTAMIVIR IN CHILDREN LESS THAN SIX MONTHS OF AGE WITH SWINE FLU DURING AN INFLUENZA PANDEMIC

The attached letter is to alert healthcare professionals to a change in the dosage regime for oseltamivir in children aged less than 6 months during an influenza pandemic outbreak.

1. Please could all Medical Directors of NHS Boards forward this message to:-
 - All General Practitioners (GPs) – please could GPs ensure this message is seen by all practice nurses and non-principals working in the practice and retain a copy in the ‘locum information pack’; and
 - Deputising Services.
2. Please could Directors of Public Health forward this message to:-
 - Chief Executives of NHS Boards
 - Consultants in Communicable Diseases & Environmental Health
3. Please could Directors of Pharmacy forward this message to:
 - Community Pharmacists; and
 - Medicines Information Pharmacists.

Thank you for your co-operation.

Yours sincerely

PROFESSOR BILL SCOTT
Chief Pharmaceutical Officer

25 November 2009

Dear Colleague

DOSAGE OF OSELTAMIVIR IN CHILDREN UNDER SIX MONTHS OF AGE WITH SWINE FLU DURING AN INFLUENZA PANDEMIC

This letter is to alert you to a change in the dosage regime for oseltamivir in children aged less than 6 months of age with swine flu during an influenza pandemic outbreak.

Background

The original treatment dose for oseltamivir in children aged less than one year was 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.

In September 2009, the manufacturers of Tamiflu (oseltamivir), Roche Products Ltd, were granted a variation to the Market Authorisation for the treatment of children aged 6 months to 12 months during an influenza pandemic meaning that Tamiflu Suspension became licensed for use in this age group. In addition, on the basis of pharmacokinetic data the recommended dose for treatment of children 6 to 12 months of age was changed to 3 mg per kg body weight twice daily for 5 days for treatment.

In our CMO / CPO letter dated 24 September 2009, notifying you of this change, we also alerted you to the fact that Roche had also submitted data to the European Medicines Regulatory Authority on the use of oseltamivir in children aged 0 to 6 months and that a decision about the dosage of Tamiflu in this age group would be made by the end of the year.

Treatment of children under 6 months of age

The European Commission has now ratified advice from the European Medicines Evaluation Agency (EMA) for a change of dosage regimen for Tamiflu (oseltamivir) for children less than 6 months of age.

The new recommended doses for treatment for children less than 6 months of age during a pandemic are:

- **newborn children up to 1 month of age:**
remains as **2 mg per kg** body weight given **twice a day** for **5 days**.
- **children over 1 month and up to 3 months of age:**
is **2.5 mg per kg** body weight given **twice a day** for **5 days**.

- **children over 3 months of age and under 6 months of age:**

is now the same as the recommended dose for those aged 6 months and over and up to 1 year of age which is **3 mg per kg** body weight given **twice a day** for **5 days**.

Supporting prescribers

There are currently two liquid formulations of oseltamivir in use in Scotland, Oseltamivir Oral Solution 15 mg/mL and Oseltamivir 12 mg/mL Suspension (the branded product Tamiflu Suspension). The Oseltamivir 15 mg/mL Solution remains unlicensed as it is manufactured as a special. 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 any remaining stocks of the 12 mg/mL Suspension from primary care.

In order to assist prescribers the current dosage information for each age group up to one year of age is included in the attached Annexes. **Annexes one to three** have tables representing the 15 mg/mL Oseltamivir Oral Solution for each of the age categories and **annexes four to six** set out the tables for the 12 mg/mL Oseltamivir Suspension (Tamiflu).

We would advise that you please destroy any previous dosage information in order to reduce the risk of any transcribing errors.

Managing the transition

General Practitioners authorising the supply of oseltamivir for children aged less than 6 months 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.

Yours sincerely

**DR HARRY BURNS
CHIEF MEDICAL OFFICER
OFFICER**

**PROFESSOR BILL SCOTT
CHIEF PHARMACEUTICAL**

ANNEX ONE

Dosage chart for oseltamivir solution 15mg/mL for children newborn up to 1 month

TREATMENT: 2mg/kg given twice a day for 5 days		
PROPHYLAXIS: 2mg/kg given once a day for 10 days		
OSELTAMIVIR solution 15mg in 1mL (20mL)		
Dose calculation based on weight and dose of 2mg/kg		
Weight range (kg)	Dose in mL of solution 15mg/mL	Quantity to be supplied
2.0 - 2.6	0.3	1 x 20 mL
2.7 - 3.3	0.4	1 x 20 mL
3.4 - 4.0	0.5	1 x 20 mL
4.1 - 4.8	0.6	1 x 20 mL
4.9 - 5.5	0.7	1 x 20 mL

ANNEX TWO

Dosage chart for oseltamivir solution 15mg/mL for children over 1 month and up to 3 months of age

TREATMENT: 2.5mg/kg given twice a day for 5 days		
PROPHYLAXIS: 2.5mg/kg given once a day for 10 days		
OSELTAMIVIR solution 15mg in 1mL (20mL)		
Dose calculation based on weight and dose of 2.5mg/kg		
Weight range (kg)	Dose in mL of solution 15mg/mL	Quantity to be supplied
3.0 - 3.5	0.5	1 x 20 mL
3.6 - 4.1	0.6	1 x 20 mL
4.2 - 4.7	0.7	1 x 20 mL
4.8 - 5.3	0.8	1 x 20 mL
5.4 - 5.9	0.9	1 x 20 mL
6.0 - 6.5	1.0	1 x 20 mL
6.6 - 7.1	1.1	1 x 20 mL
7.2 - 7.7	1.2	1 x 20 mL

ANNEX THREE

Dosage chart for oseltamivir solution 15mg/mL for children over 3 months and less than 1 year of age

TREATMENT: 3mg/kg given twice a day for 5 days		
PROPHYLAXIS: 3mg/kg given once a day for 10 days		
OSELTAMIVIR solution 15mg in 1mL (20mL)		
Dose calculation based on weight and dose of 3mg/kg		
Weight range (kg)	Dose in mL of solution 15mg/mL	Quantity to be supplied
4.5 - 4.9	0.9	1 x 20 mL
5.0 - 5.4	1.0	1 x 20 mL
5.5 - 5.9	1.1	1 x 20 mL
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 FOUR

Dosage chart for oseltamivir (Tamiflu) suspension 12mg/mL for children newborn up to 1 month of age

TREATMENT: 2mg/kg given twice a day for 5 days	
PROPHYLAXIS: 2mg/kg given once a day for 10 days	
OSELTAMIVIR (Tamiflu) suspension 12mg in 1mL (75mL)	
Dose calculation based on weight and dose of 2mg/kg	
Weight range (kg)	Dose in mL of suspension 12mg/mL
2.0 - 2.1	0.3
2.2 - 2.7	0.4
2.8 - 3.3	0.5
3.4 - 3.9	0.6
4.0 - 4.5	0.7
4.6 - 5.1	0.8
5.2 - 5.5	0.9

ANNEX FIVE

Dosage chart for oseltamivir (Tamiflu) suspension 12mg/mL for children over 1 month and up to 3 months of age

TREATMENT: 2.5mg/kg given twice a day for 5 days	
PROPHYLAXIS: 2.5mg/kg given once a day for 10 days	
OSELTAMIVIR (Tamiflu) suspension 12mg in 1mL (75ml)	
Dose calculation based on weight and dose of 2.5mg/kg	
Weight range (kg)	Dose in mL of suspension 12mg/mL
3.0 - 3.3	0.6
3.4 - 3.8	0.7
3.9 - 4.3	0.8
4.4 - 4.7	0.9
4.8 - 5.2	1.0
5.3 - 5.7	1.1
5.8 - 6.2	1.2
6.3 - 6.7	1.3
6.8 - 7.1	1.4
7.2 - 7.6	1.5
7.7 - 7.9	1.6

ANNEX SIX

Dosage chart for oseltamivir (Tamiflu) suspension 12mg/mL for children over 3 months and less than 1 year of age

TREATMENT: 3mg/kg given twice a day for 5 days	
PROPHYLAXIS: 3mg/kg given once a day for 10 days	
OSELTAMIVIR (Tamiflu) suspension 12mg in 1mL (75ml)	
Dose calculation based on weight and dose of 3mg/kg	
Weight range (kg)	Dose in mL of suspension 12mg/mL
4.5 - 4.7	1.1
4.8 - 5.1	1.2
5.2 - 5.5	1.3
5.6 - 5.9	1.4
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