

Gateway ref: 13032**CAS ref: CEM/CMO/2009/32**

20 November 2009

Dear Colleague

Dosage of oseltamivir in children under 6 months of age in the swine flu pandemic

As indicated in our letter of 24 September 2009 (Gateway Reference: 12664), we are now in a position to tell you about changes to the dose of oseltamivir in children under 6 months of age during an influenza pandemic outbreak and the steps that need to be taken to ensure a safe transition to the new dosage.

Treatment of Children aged under 6 months of age

The manufacturer of Tamiflu (oseltamivir), Roche Products Ltd, has been granted a variation to the Market Authorisation for the treatment of children under 6 months of age.

The recommended dose for the **treatment** of newborn children up to 1 month of age remains as:

2 mg per kg body weight given twice a day for 5 days.

The recommended dose for the **treatment** of 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

The recommended dose for the **treatment** of 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 under 1 year of age:

3 mg per kg body weight given twice a day for 5 days

The liquid formulation of oseltamivir in the national stockpile is Oseltamivir Oral Solution. This has a strength of 15mg in 1ml and is manufactured by designated licensed hospital pharmacy manufacturing units. It is the product that should be routinely used for the treatment of swine flu in children under 1 year. Set out in the table, included at **Annex One**, is new dosage guidance based on the 15mg in 1ml Oseltamivir Oral Solution. To make authorisation and issuing easier, PCTs have been asked to quarantine the lower strength 12mg in 1ml Oseltamivir Suspension.

Managing the transition

General Practitioners and healthcare professionals authorising the supply of oseltamivir for children aged under 6 months of age, and those making the supply from antiviral collection points will need to ensure extra care is taken as this change of dosage is implemented. The implementation should be overseen and supervised by PCT Chief Pharmacists working closely with PCT Directors of Public Health.

The Department of Health is issuing two new authorisation vouchers for the supply of oseltamivir for the treatment of children under 1 year during an influenza pandemic. One for children up to 3 months of age and one for children over 3 months of age and under 1 year of age. The new vouchers reflect the agreement reached with the RCGP and BMA in relation to the safe authorisation and supply of antivirals. The new vouchers are now being distributed to GPs directly and should be received by 14 December 2009.

Pre-existing vouchers based on the previous doses should continue to be used until the new vouchers are received. The new vouchers should start to be used as soon as they are received with the previous vouchers then being destroyed.

We are not expecting any further changes to the dose of oseltamivir in the near future but will keep you updated if there are any changes.

Prophylaxis

The vouchers allow for the possibility of prophylaxis. This recognises that 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. **The doses for prophylaxis are shown in the tables in Annex One.**

The dose recommendations were based on limited evidence to support the use of oseltamivir for the prevention of influenza for children under the age of one year. Doctors should 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.

We hope this information is helpful.

Yours sincerely,

A handwritten signature in black ink, appearing to read 'Liam Donaldson'.

Sir Liam Donaldson
Chief Medical Officer

A handwritten signature in black ink, appearing to read 'K.W. Ridge'.

Dr Keith Ridge
Pharmaceutical Officer

ANNEX ONE

Dosage chart for 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 1 ml		
Dose calculation based on weight and dose of 2 mg/kg		
Weight range in kg	Dose to be given in 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

Doses have been rounded off to 0.1 ml increments to make it easier for antiviral collection points and parents to administer the medicine.

Dosage chart 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 1 ml		
Dose calculation based on weight and dose of 2.5 mg/kg		
Weight range in kg	Dose to be given in 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

Doses have been rounded off to 0.1 ml increments to make it easier for antiviral collection points and parents to administer the medicine.

Dosage chart for children over 3 months and under 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 1 ml		
Dose calculation based on weight and dose of 3 mg/kg		
Weight range in kg	Dose to be given in 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

Doses have been rounded off to 0.1 ml increments to make it easier for antiviral collection points and parents to administer the medicine.