

Gateway reference: 12664

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 and the steps that need to be taken to ensure a safe transition to the new dosage.

Up to now, the treatment dose for oseltamivir in children under 1 has been 2mg/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. 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

The liquid formulation of oseltamivir in the national stockpile is Oseltamivir Oral Solution 15mg in 1ml and is the product that should be routinely used for treatment of swine flu in children under 1 year. There may also be a very limited amount of the Roche product Tamiflu (oseltamivir) suspension 12mg in 1ml in the normal medicines supply chain. Set out in the table, included at **Annex One**, is new dosage guidance based on the 15mg in 1ml Oseltamivir Oral Solution

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 i.e 2mg/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**

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 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. 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 9 October 2009.


Prophylaxis

The new vouchers also 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.

However, 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. 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.

The new vouchers should start to be used as soon as they are received during the next two weeks with the previous vouchers then being destroyed.

Yours sincerely

A handwritten signature in black ink, appearing to read 'Liam Donaldson', written in a cursive style.

**SIR LIAM DONALDSON
CHIEF MEDICAL OFFICER**

A handwritten signature in black ink, appearing to read 'K.W. Ridge', written in a cursive style.

**DR KEITH RIDGE
CHIEF PHARMACEUTICAL OFFICER**

ANNEX ONE

Dosage chart for children 6 months and over and up to one 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
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 children under 6 months of age

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
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