Victoria Government Gazette

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Drugs Poisons and Controlled Substances Act 1981
Section 22D

PUBLIC HEALTH EMERGENCY ORDER

I, Fran Thorn, Secretary to the Department of Human Services, make this public health emergency order in the belief that it is necessary to do so in order to respond to the occurrence of a number of cases of human infection with H1N1 Influenza A 09 (human swine influenza) in metropolitan Melbourne.

By this Order I authorise all nurses registered in Division 1 of the Register kept by the Nurses Board of Victoria under the **Health Professions Registration Act 2005** to obtain and possess, use and supply the Schedule 4 poison Oseltamivir. Use and supply of the nominated drug is to be in accordance with the attached Schedule.

This order comes into force on 25 May 2009 and shall continue in force until midnight 27 July 2009.

FRAN THORN
Secretary to the Department of Human Services

SCHEDULE

DETAILS OF DOSAGE AND ADMINISTRATION OF
OSELTAMIVIR (TAMIFLU) FOR PROPHYLACTIC TREATMENT

Indication	**Prophylactic Treatment** of individuals who have been identified by Department of Human Services Contact Tracers as having been exposed to a case of human infection due to H1N1 Influenza A 09 (human swine influenza). Treatment should commence as soon as possible after referral by DHS Contact Tracer.	
Symptoms	Not relevant.	
Presentation	**75 mg** capsule (for adults); **12 mg/ml** oral suspension (for children).	
Prophylaxis dose	**For adults and adolescents** **75 mg** once daily for 10 days **For children >1 year of age** ≤15 kg: 30 mg (2.5 mL) >15 to 23 kg: 45 mg (3.75 mL) >23 to 40 kg: 60 mg (5 mL) >40 kg: 75 mg (one capsule) **once daily for 10 days.**	**For children < 1 year of age** ≤3 months: Not recommended unless the situation is deemed critical 3 – 11 months: 2 mg/kg once daily for 10 days

Labelling, requirements	The container in which the Oseltamivir is supplied must be clearly labelled with (a) the name of the patient; and (b) the date of supply; and (c) the name, address and telephone number of the place of supply; and (d) the word Oseltamivir or a trade name which unambiguously identifies the capsules or oral suspension as such and its strength, form and quantity; and (e) the directions for use.
Storage requirements	A person authorised by this Order must keep all supplies of Oseltamivir in their possession in a lockable storage facility; and take all reasonable steps to ensure that the storage facility remains locked and secured to prevent access by an unauthorised person at all times, except when it is necessary to open it to carry out an essential operation in connection with use or supply in accordance with this Order.
Record Keeping requirements	A person authorised by this Order must make the following record of each use or supply of Oseltamivir: (a) the date of the transaction; and (b) the name, form, strength and quantity of the Oseltamivir; and (c) the name and address or location of persons to whom the Oseltamivir is transferred, supplied, administered or otherwise disposed of; and (d) in the case of a transaction involving supply or administration to a specific person, the name of the person to whom the supply or administration was made, and the name of the person carrying out the transaction. The records must be maintained, in English, in readily retrievable form, and kept for not less than 3 years from the date of the transaction. The records must be produced on demand to the Secretary to the Department of Human Services or her delegate. A person authorised by this Order must notify the Secretary without delay of the circumstances of any loss, destruction or theft of any Oseltamivir held by them, or of any records kept by the person relating to Oseltamivir.
Contraindications	Creatinine clearance <10 ml/min, routine haemodialysis or continuous peritoneal dialysis, hypersensitivity to Oseltamivir or components, fructose intolerance (oral suspension).
Precautions[1]	Creatinine clearance between 10 and 30 ml/min, pregnant and breast-feeding women (Category B1).
Drug interactions	No significant interactions known.
Side effects	Nausea and vomiting (in approximately 10%), insomnia, headache, fatigue, neuropsychiatric events have been reported.
Administration	As a result of reported gastrointestinal upset, it is recommended that oseltamivir be taken with food. Gastrointestinal upset is most often associated with the first dose.

Special information for children < 1 year of age:	**Use of Oseltamivir for prophylaxis in infants less than 3 months of age is NOT recommended unless the situation is critical due to limited data on use in this age group.** **Precautions:** Care must be taken in prescribing in patients with impaired renal function, and in infants less than seven days old. Wider spacing of doses may be required. **Basis of precautions:** Data on weaning rats given the equivalent of 1000 mg/kg with evidence of greater CSF penetration and potential neurotoxicity. Oseltamivir has recently been approved for use in infants by the US Food and Drug Administration (FDA) under an Emergency Use Authorisation.

[1] Tamiflu is classified as a Category B1: Drug which has been taken by only a limited number of pregnant women and women of childbearing age, without an increase in the frequency of malformation or other direct or indirect harmful effects on the human foetus having been observed. Studies in animals have not shown evidence of an increased occurrence of foetal damage.

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