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## Interim Guidance for emergency use of oseltamivir (Tamiflu®) In children under one year of age in the context of 2009 (H1N1) pandemic

The following guidance should be read in conjunction with relevant provincial and territorial guidance documents. The Public Health Agency of Canada will be posting regular updates and related documents at [www.phac-aspc.gc.ca](http://www.phac-aspc.gc.ca).

### Introduction

This guidance document has been prepared by the Public Health Agency of Canada to assist clinicians in the management of children under one year of age presenting with Influenza-like-illness (ILI) in the context of the (H1N1) 2009 pandemic. It is based on current scientific evidence, expert opinion and Health Canada's Interim Order regarding the expanded use of oseltamivir for the novel influenza A H1N1 virus in children under 1 year of age. <sup>[7]</sup> Although there are limited data supporting the use of Tamiflu® in children under one, there now exists an urgent need for recommendations to treat this population, given this group's increased risk for morbidity and mortality from influenza. Similar actions have also been taken internationally by the US FDA <sup>[3]</sup> and the EMEA <sup>[4]</sup>. This guidance is subject to review and change as new information becomes available. These guidelines should be used in conjunction with guidance contained in the [H1N1 PHAC Guidelines for health professionals](#), [Annex E](#) and [Annex G](#) of the Canadian Pandemic Influenza Plan.

### Influenza and children

Healthy children under 24 months and children with certain chronic health conditions are at increased risk of influenza-related complications and hospitalization from influenza. <sup>[1]</sup> Recent Canadian epidemiological data shows higher rates of hospitalization, ICU admissions and deaths in children under 1 compared with all H1N1 cases in Canada. Young children usually have higher temperatures and may have febrile seizures. Unexplained fever may be the only manifestation of the disease in infants. In infants less than 2 months old, the condition can progress rapidly to severe illness. Children 3 years and younger may experience nausea, vomiting, diarrhea and abdominal pain. Up to 20% of infants and may also present with neurologic symptoms suggestive of meningitis or encephalitis. <sup>[2]</sup>

### CLINICAL MANAGEMENT of children under 1 year of age

Antivirals can reduce complications and mortality from influenza. Currently, the novel H1N1 virus is susceptible to oseltamivir (Tamiflu®) and zanamivir (Relenza®), but resistant to amantadine. Relenza® is indicated only in children 7 years or older. Health Canada's Interim Order permits the expanded use of oseltamivir as a treatment or prophylaxis for children under 1 year of age, for infection caused by the pandemic (H1N1) 2009 virus due to recent clinical data suggesting its comparable safety profile identified in children over 1. <sup>[5]</sup> Adverse event data regarding use in children over 1 year of age is available in the Product Monograph. <sup>[6]</sup> After a careful assessment, antivirals may be prescribed with clinical discretion providing the potential benefits to the health of the infant outweigh the risks. The parents or guardian should be informed that this is exceptional use. This may apply to suspect cases where rapid test is positive, febrile children without another clear cause and a positive contact history, and febrile infants with respiratory compromise. If oseltamivir is prescribed, the following dosing is recommended:

#### Treatment:

Weight: 2 mg/kg BID x 5 days

If weight measures are unavailable:

0- < 3 months:	12 mg twice daily for 5 days
3- < 6 months:	20 mg twice daily for 5 days
6- < 12 months:	25 mg twice daily for 5 days

Paediatric suspension should be given if available; if not, refer to "Emergency Compounding of an oral suspension from Tamiflu® capsules" on page 16 of the [product monograph](#). [6] Children under 1 year of age with influenza should be treated in hospital. If during the H1N1 pandemic demands on hospital resources become too great, hospitalization is still indicated in children less than 3 months, due to their increased risk of progressing rapidly to severe disease. Treatment should be started as soon as possible; benefit wanes if treatment is initiated after 48 hours of the onset of symptoms.

### Prophylaxis:

Prophylactic use of antivirals other than for outbreak control in closed settings are NOT an approved use of the National Antiviral Stockpile. If, after a careful risk/benefit assessment this is thought to be clinically indicated for a particular patient, antivirals would need to be prescribed through the usual means (i.e., obtained through a pharmacy).

Weight: 2 mg/kg daily x 10 days

If weight measures are unavailable:

0- < 3 months:	Not recommended for use at this time*
3- < 6 months:	20 mg once daily for 10 days
6- < 12 months:	25 mg once daily for 10 days

*\*Note that based on the available data, prevention of influenza in infants under 3 months of age is not recommended at this time unless there has been significant exposure and/or the risk of severe illness is considered to be high. In children, viral shedding may continue for up to 14 days after the onset of influenza illness. Therefore, if the index case is a child, prophylaxis with TAMIFLU® may continue for up to 14 days.*


### Adverse Reaction Reporting

Reports of adverse reactions to antiviral medications are important as this information will be used to guide their safe and effective use, particularly in certain populations where there may only be limited safety data available, for example pregnant women and children <1. Please promptly report any suspected serious adverse reactions involving an antiviral medication to Health Canada at: [Adverse reaction reporting, Marketed Health Products](#) or call: **1-866-234-2345**. [8]




The Interim Order regarding the expanded use of Tamiflu® for children under one year of age applies to all strengths and formulations:

DIN#02304848, 30mg capsule  
 DIN#02304856, 45mg capsule  
 DIN#02241472, 75mg capsule  
 DIN#02245549, 12mg/ml (reconstituted) oral suspension

### References and resources:

1. National Advisory Committee on Immunization. [Statement on influenza vaccination for the 2007-2008 season](#). *Canadian Communicable Disease report 2008*; 34:10-14.
2. Public Health Agency of Canada. [Canadian Pandemic Influenza Plan for the Health Sector: Annex G Clinical Care Guidelines and Tools](#). 2008; 16.
3. US FDA. [Tamiflu Emergency Use letter April 2009](#). Available at: <http://www.fda.gov/downloads/Drugs/DrugSafety/InformationbyDrugClass/UCM143872.pdf> 
4. European Medical Agency. [Follow-up Recommendations from CHMP on Novel Influenza \(H1N1\) outbreak](#) .May 2009. Available at: <http://www.emea.europa.eu/humandocs/PDFs/EPAR/tamiflu>

/32609509en.pdf 

5. Okamoto S , Kamiya I , Kishida K et al. Experience with Oseltamivir for Infants Younger than 1 year old in Japan. *Pediatric Infectious Disease Journal*;24:931-932.
6. Roche Canada. *Tamiflu product monograph*. July 2009. Available at: [http://www.rochecanada.com/portal/eipf/ca/portal/roche/consumer\\_information;jsessionid=KIX2hJpc6hXp8gQ1mb6RSpV5WLWf2LVhpZsDN2CrZGvC1JC2Q64M!792815078?paf\\_gear\\_id=17700009&paf\\_pageId=re7191019&glossary\\_id=static/glossary/re7300002/re77300002/re77300003/re753001/Definition\\_01049.content](http://www.rochecanada.com/portal/eipf/ca/portal/roche/consumer_information;jsessionid=KIX2hJpc6hXp8gQ1mb6RSpV5WLWf2LVhpZsDN2CrZGvC1JC2Q64M!792815078?paf_gear_id=17700009&paf_pageId=re7191019&glossary_id=static/glossary/re7300002/re77300002/re77300003/re753001/Definition_01049.content) 
7. Interim Order Respecting the Sale of Oseltamivir Phosphate – Expanded Use for Children Under 1 Year of Age 
8. Reporting Adverse Reactions to Antiviral Drugs During an Influenza Pandemic - Guidelines for Health Professionals and Consumers. Located at: [http://www.hc-sc.gc.ca/dhp-mps/pubs/medeff/\\_guide/2009-ar-ei\\_anti\\_guide-ldir/index-eng.php](http://www.hc-sc.gc.ca/dhp-mps/pubs/medeff/_guide/2009-ar-ei_anti_guide-ldir/index-eng.php) 

Date Modified: 2009-07-20