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Reporting Adverse Reactions to Antiviral Drugs During an Influenza Pandemic – Guidelines for Health Professionals and Consumers

Revised: May 29, 2009

Canada Vigilance Program

ADVERSE REACTIONS
SIDE EFFECTS
WARNINGS
GUIDELINES

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What is an Influenza Pandemic?

People are exposed to different strains of the influenza virus many times during their lives. Even though the virus changes over time, previous bouts of influenza may offer some protection against infection caused by a similar strain of the virus.

However, three to four times each century, for unknown reasons, a radical change takes place in the influenza A virus causing a new strain to emerge. Since people have no protection against the new strain, it can spread rapidly around the world, causing what is known as a pandemic. The pandemic influenza virus may cause severe complications, such as pneumonia and death in previously healthy individuals.

For more information about pandemic influenza consult the Public Health Agency of Canada Web site at www.fightflu.ca.

What are Antiviral Drugs?

Antiviral drugs, such as oseltamivir (Tamiflu®), zanamivir (Relenza®) and amantadine, are used for the prevention and early treatment of influenza, and are expected to be widely used if there is an influenza pandemic, particularly since a pandemic influenza vaccine is unlikely to be available in the early months of a pandemic.

Antiviral drugs, when taken early in the illness (within 48 hours) can reduce influenza symptoms, shorten the length of illness and potentially reduce the serious complications of influenza. As well, antiviral drugs may prevent influenza infection if they are taken during periods of potential exposure to the virus. Antiviral drugs can come in pill, syrup/liquid, or inhaler form.

Vaccines are the primary means to prevent illness from influenza. They stimulate the production of antibodies against the flu virus, providing immunity against the virus. At the start of an influenza pandemic, it may take several months before a new vaccine can be developed. Antiviral drugs are not a vaccine

Antiviral drugs are assessed by Health Canada for safety, effectiveness and quality before they can be sold in Canada. Once approved, they are assigned an eight-digit Drug Identification Number (DIN).

Why Report Adverse Reactions to Antiviral Drugs?

Health Canada continues to monitor the safety profile of the health products sold in Canada, to ensure that the benefits of using the product continue to outweigh the risks that may be associated with its use. Some of these risks are known at the time the drug is approved, but we also know that additional information about risks can only become known once the product is more widely used.

At this point in time, serious adverse reactions to antiviral drugs have been very rare. However, during a pandemic it will be essential to look for and respond to any serious adverse reactions that may occur with widespread use of these drugs, as this information will help guide the safest and most effective use of these drugs.

During an influenza pandemic, Health Canada will make the assessment of suspected adverse reactions to antiviral medications a priority, to ensure that any new safety concerns are identified and communicated quickly to help inform the appropriate use of these products.

What to Report

All serious suspected adverse reactions should be reported. A serious adverse reaction is one that:

- results in a death;
- is life-threatening;
- causes congenital malformation or birth defect;
- results in persistent or significant disability or incapacity;
- requires in-patient hospitalization or prolongation of existing hospitalization.

To assist in the assessment of the adverse reaction reports as much information as possible should be provided in the report. Please include the following details where possible:

- whether the antiviral drug was used for **prevention or treatment** of influenza;
- the age and sex of the patient;
- any medical conditions or problems the patient had prior to starting the antiviral;
- any prescription, over the counter or natural health products that the patient had been taking prior to starting or while taking the anti-viral;
- the results of laboratory tests or investigations done as a result of the adverse reaction;
- any treatment of the reaction, including if the antiviral was discontinued;
- the outcome of the adverse reaction.

Although every adverse reaction report is important, reporting all suspected adverse reactions may not be feasible due to the impact of the influenza pandemic on the health care system and the daily life of Canadians in general. The most important information to report will be those most serious adverse reactions that may impact on the decision to use one or more of the antiviral drugs for the prevention or treatment of influenza.

How to Report

Health professional and the general public are encouraged to use one of the following three methods to report an adverse reaction to Health Canada:

- By calling toll-free at **1-866-234-2345**;
- Online at www.healthcanada.gc.ca/medeffect
- By completing a Canada Vigilance Reporting Form which you can send by **fax toll-free to 1-866-678-6789**.

Alternatively, the Canada Vigilance Reporting Form can be sent by **postage paid mail**.

The form and postage paid label are available at www.healthcanada.gc.ca/medeffect or by calling **1-866-234-2345**. The adverse reaction reporting form is also available for health professionals at the back of the *Compendium of Pharmaceuticals and Specialties (CPS)*.

More Information

The Canada Vigilance Program at Health Canada is responsible for the collection and assessment of adverse reaction reports that have been submitted by health professionals or consumers; the first phase of the post market surveillance continuum. Information from domestic adverse reaction reports is essential to monitoring the safety of health products. Adverse reaction reports help us to identify, assess and inform Canadians of new health product safety issues. Having access to the latest safety information helps Canadians make informed decisions about the use of drugs and health products.

The Canada Vigilance Online Database can be used to retrieve essential information from adverse reaction reports. It is available at www.healthcanada.gc.ca/medeffect and is intended solely to provide health product information as reported to Health Canada. It cannot be used on its own to evaluate a health product's safety profile and does not provide conclusive information on the safety of health products.

Additional information for health professionals and consumers regarding adverse reaction reporting may be found in the guidance document entitled *Guidelines for the Voluntary Reporting of Suspected Adverse Reactions to Health Products by Health Care Professionals and Consumers*, located on the *MedEffect Canada* section of the Health Canada Web site at: www.healthcanada.gc.ca/medeffect.

For more information on the Canada Vigilance Program, health professionals and consumers may contact the appropriate Canada Vigilance Regional Office listed below. The following toll-free numbers may also be used. Calls will be automatically routed to the appropriate Canada Vigilance Regional Office based on the area code from which the call originates.

Telephone (toll-free): 1-866-234-2345

Fax (toll-free): 1-866-678-6789

British Columbia and Yukon

Canada Vigilance Regional Office - British
Columbia and Yukon
Health Canada
400 - 4595 Canada Way,
Burnaby, British Columbia V5G 1J9
CanadaVigilance_BC@hc-sc.gc.ca

Alberta and Northwest Territories

Canada Vigilance Regional Office - Alberta
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Health Canada
Suite 730, 9700 Jasper Avenue
Edmonton, Alberta T5J 4C3
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Saskatchewan

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Saskatchewan
Health Canada
4th floor, Room 412
101 - 22nd Street East
Saskatoon, Saskatchewan S7K 0E1
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Manitoba

Canada Vigilance Regional Office –
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Health Canada
510 Lagimodière Blvd
Winnipeg, Manitoba R2J 3Y1
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Ontario and Nunavut

Canada Vigilance Regional Office - Ontario
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Health Canada
2301 Midland Avenue
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Quebec

Canada Vigilance Regional Office - Quebec
Health Canada
1001 Saint-Laurent Street West,
Longueuil, Québec J4K 1C7
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**New Brunswick, Nova Scotia, Prince
Edward Island and, Newfoundland and
Labrador**

Canada Vigilance Regional Office - Atlantic
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