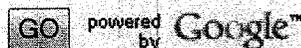


**U.S. Food and Drug Administration**Department of
Health and
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Influenza (Flu) Antiviral Drugs and Related Information

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Introduction

The term "influenza" refers to illness caused by influenza virus. This is commonly also called "flu", but many different illnesses cause "flu-like" systemic and respiratory symptoms such as fever, chills, aches and pains, cough, and sore throat. In addition, influenza itself can cause many different illness patterns, ranging from mild common cold symptoms to typical "flu" to life-threatening pneumonia and other complications, including secondary bacterial infections.

This web site contains links to several sources of general information about influenza. Because vaccination is the primary means of preventing and controlling influenza, links related to influenza vaccine are listed first, followed by links related to antiviral drugs that have been approved in the United States for influenza. After the vaccine and antiviral drug links, there is a list of web sites that provide additional influenza information from United States government agencies and the World Health Organization, and a list of contacts for further inquiries.

Information provided on this web site may change frequently, and should not be used as a substitute for individual evaluation by a health care provider, or as the primary means of diagnosing influenza or determining treatment.

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Influenza Vaccine Information

Influenza vaccine is the principal method of preventing and controlling influenza. The following links provide information on general uses of vaccines and on current supply issues.

- [Center for Biologics Evaluation and Research \(CBER\)](#). This web page links to information on influenza virus vaccine.
- [Influenza \(Flu\): Protect Yourself and Your Loved Ones](#). Comprehensive flu information

from the Centers for Disease Control.

- Centers for Disease Control and Prevention - National Immunization Program. *Influenza Vaccine: What you need to know.* This consumer pamphlet contains basic vaccine questions and answers.

Drug Information

Uncomplicated influenza gets better with or without treatment, but may cause substantial discomfort and limitation of activity before getting better. Complications of influenza can include bacterial infections, viral pneumonia, and cardiac and other organ system abnormalities. People with chronic medical conditions may have increased risk of complications when they get influenza. Many other diseases, including serious infections such as rapidly progressive bacteremias, may start with symptoms that resemble influenza and may need to be considered in treatment decisions. Rapid laboratory tests can help in detecting influenza but do not exclude the possibility of other illnesses or take the place of clinical evaluation.

Many people with uncomplicated influenza use over-the-counter medicines to help lessen their symptoms. Antiviral drugs can also help to reduce the time it takes for symptoms to improve in uncomplicated illness caused by influenza virus. Recent increases in the number and promotion of antiviral drugs for influenza have increased interest in the role of specific antiviral drugs for this condition.

Complications of influenza, and other illnesses that resemble influenza, may require different treatment and may need urgent medical attention. Use of antiviral drugs does not eliminate the risk of complications, and some complications (as well as other medical conditions that could be confused with influenza) can be life-threatening. In addition, influenza viruses can become resistant to specific anti-influenza antiviral drugs, and all of the drugs have side effects. Therefore, if you have new symptoms during treatment, or your symptoms persist or get worse during treatment, you should see your health care provider.

There has been a lot of recent concern about "bird flu" which can refer to a number of influenza viruses that occur in birds and could become causes of human disease in some situations. Some of the current influenza antiviral drugs are able to inhibit many of the "bird flu" viruses in the laboratory although it is not known exactly how much effect they would have against these infections in people.

The following links lead to information such as trade names, package inserts, and other material related to the four antiviral drugs currently approved by FDA to treat acute, uncomplicated influenza. Two related drugs, amantadine (approved 1966; Trade Name Symmetrel, also available as generic Amantadine Hydrochloride) and rimantadine (approved 1993; Trade Name Flumadine, also available as generic Rimantadine Hydrochloride), are approved for treatment and prevention of influenza A. Two newer drugs, zanamivir (approved 1999; Trade Name Relenza; no approved generics) and oseltamivir phosphate (approved 1999; Trade Name Tamiflu; no approved generics), are approved for treatment of acute uncomplicated illness due to influenza A and B. Oseltamivir has been approved also for preventive use, while zanamivir is approved only for treatment. Approved ages, doses, and uses in children are different for each drug, so the individual package inserts should be checked for this information. **The anti-influenza antiviral drugs are not a substitute for vaccine and are used only as an adjunct to vaccine in the control of influenza.**

The antiviral drug information addresses side effects or adverse events that might be associated with each drug. Because some side effects can be serious and because viruses may become resistant when antiviral drugs are used indiscriminately, decisions on the use of these drugs should be based on individual evaluations of risk and benefit. **FDA encourages reporting of serious adverse events (associated with these or any other drugs) to the MedWatch program to facilitate continued updating of risk/benefit information.**

- [Symmetrel \(amantadine\)](#). Approval, review, and labeling information from Drugs@FDA.
- [Flumadine \(rimantadine\)](#). Approval, review, and labeling information from Drugs@FDA.
- [Relenza \(zanamivir\)](#). Approval, review, and labeling information from Drugs@FDA, plus consumer information, and Dear Health Professional letter regarding updated safety information.
- [Tamiflu \(oseltamivir phosphate\)](#). Approval, review, and labeling information from Drugs@FDA, plus consumer information.
- [CDC Recommends Against the Use of Amantadine and Rimantadine for the Treatment or Prophylaxis of Influenza in the United States During the 2005–06 Influenza Season](#). [CDC Health Alert](#). (1/14/2006)
- [Office of Generic Drugs - Statement on Expedited Review of Generic Drug Products for the Prophylaxis and Treatment of Illness Caused by Various Strains of the Influenza Virus](#). (10/18/2004)
- [MedWatch site for Adverse Event Reporting](#). Information and instructions for reporting of adverse events associated with medical products such as prescription or nonprescription drugs, biologics, and medical devices.
- [Electronic Orange Book](#) This resource can be searched for holders of approved or discontinued marketing applications, especially for drugs that may have more than one source of generic preparations.
- [Public Health Advisory: Safe and Appropriate Use of Influenza Drugs](#). (Issued 1/12/2000). Health professionals, especially prescribers, are reminded of important clinical decisions that need to be made when considering use of anti-viral drugs for signs and symptoms of influenza.
- [Talk Paper: FDA Reminds Prescribers of Important Considerations before Prescribing Flu Drugs](#) (Issued 1/12/00).
- [Letter from the Glaxo Wellcome, Inc. on Relenza \(zanamivir for inhalation\)](#). (Issued 7/2000). Optional format: PDF. This letter notifies health professionals of important revisions to the safety labeling for Relenza. The labeling has been revised to more clearly reflect that serious respiratory adverse events have been reported in patients with or without known underlying respiratory disease, and to incorporate additional updated safety information.
- [A Look at the 2003-2004 Flu Season](#). March-April, 2004 *FDA Consumer* magazine article on influenza prevention and treatment.
- [Information on Approaches to Drug Development for Emerging Viral Infections](#)

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Influenza Information from Other Web Sites

- [FDA Flu Information Page](#). Information on flu prevention and treatment with vaccines and antiviral drugs.
- [Cautions in Using Rapid Tests for Detecting Influenza A Viruses](#). This Safety Tip for

Laboratorians from the FDA Center for Devices and Radiological Health provides information about rapid influenza tests currently available in the US market, their uses and limitations for detecting Influenza A viruses, and their performance implications.

- [Influenza \(flu\): Protect yourselves and your loved ones. Information for consumers and healthcare professionals from the Centers for Disease Control and Prevention \(CDC\).](#)
- [World Health Organization \(WHO\) Influenza Information.](#) This web page provides links to WHO fact sheets, plus global surveillance and outbreak information.
- [National Institute of Allergy and Infectious Diseases. NIAID's flu and cold publications page.](#)
- [National Vaccine Program Office.](#) Influenza pandemics can occur when a novel strain of virus causes an epidemic that spreads over a wide geographic area and affects an exceptionally high proportion of the population. This web site contains information about influenza, pandemics, and the Draft Pandemic Influenza Preparedness and Response Plan.
- [PandemicFlu.gov.](#) The official U.S. government Web site for information on pandemic flu and avian influenza.

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Contacts for More Information

Information on availability of influenza vaccine:

Food and Drug Administration
Center for Biologics Evaluation and Research
Office of Communication, Training & Manufacturers Assistance
301-827-1800. Fax: 301-827-3843
octma@cber.fda.gov

Information on drugs used to treat influenza:

Food and Drug Administration
Center for Drug Evaluation and Research
Drug Information Line
888-info-FDA or 301-827-4573. Fax: 301-827-4577
druginfo@cder.fda.gov

Information on influenza prevention and control:

Centers for Disease Control and Prevention
Public Inquiries Office
800-311-3435 or 404-639-3311. Fax: 770-488-4995
inquiry@cdc.gov

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