

EMERGENCY USE AUTHORIZATION of RELENZA®: FACT SHEET FOR PATIENTS AND PARENTS/CAREGIVERS

You have been given RELENZA® (zanamivir) for either treatment or prevention of 2009 H1N1 flu (used to be called Swine Influenza A or Swine Flu). You can decide whether or not to take this drug. Taking RELENZA® may help you or your child recover more quickly if you or your child have 2009 H1N1; or RELENZA® may help keep you or your child from getting sick if you or your child have been exposed to the 2009 H1N1 flu virus.

What is 2009 H1N1 flu?

The 2009 H1N1 flu is a new flu virus causing illness in people. This new virus was first detected in people in the United States in April 2009. This virus is spreading from person-to-person worldwide, probably in much the same way that regular seasonal flu viruses spread.

What are the signs and symptoms of 2009 H1N1 flu in people?

The symptoms include fever, cough, sore throat, runny or stuffy nose, body aches, headache, chills and fatigue. Some people may have diarrhea and vomiting. People may be infected with the flu, including 2009 H1N1 flu, and have respiratory symptoms without fever. Like seasonal flu, 2009 H1N1 flu may cause worsening of underlying chronic medical conditions like asthma and heart disease. Severe illnesses and death associated with this virus have been reported.

What is RELENZA®?

RELENZA® is a medicine that is approved by the U.S. Food and Drug Administration (FDA) to treat and prevent influenza. The FDA-approved package insert on RELENZA® can be found via Drugs@FDA on <http://www.accessdata.fda.gov/scripts/cder/drugsatfda/index.cfm>.

Why is RELENZA® being used under an Emergency Use Authorization (EUA)?

An EUA is issued by the FDA to allow RELENZA® to be used in more ways during this emergency involving 2009 H1N1 flu. For more information, visit <http://www.cdc.gov/h1n1flu/eua/relenza.htm> or <http://www.fda.gov>.

Who should not take RELENZA®?

Do not take RELENZA® if you have ever had a severe allergic reaction to RELENZA® or lactose. RELENZA® is not recommended for people with chronic lung disease such as asthma or COPD. RELENZA® should only be used for treatment of persons aged 7 years and older, and for prevention in persons aged 5 years and older. It should not be used for prevention of flu in nursing home patients.

What is the dose of RELENZA®?

- **For Treatment:** 10 mg (2 inhalations) twice daily for 5 days
- **For Prevention:** Household Setting: 10 mg (2 inhalations) once daily for 10 days
Community Outbreaks: 10 mg (2 inhalations) once daily for 28 days

Therapy should begin as soon as possible after exposure or onset of symptoms, and be taken at approximately the same time each day.

How should RELENZA® be taken?

RELENZA® is packaged in a medicine disk called a Rotadisk® and is inhaled by mouth using a delivery device called a Diskhaler®. Each Rotadisk® contains 4 blisters. Each blister contains 5 mg of active drug and 20 mg of lactose powder (which contains milk proteins). Each packaged box of RELENZA® contains 5 Rotadisks (total of 10 doses) and a Diskhaler® inhalation device. Read the "Patient Instructions for Use" in the package and refer to your health care provider for instructions on how to use the Diskhaler®. RELENZA® should be given to children only under adult supervision and instruction.

What are the possible benefits of taking RELENZA®?

If used for treatment, RELENZA® can benefit by stopping the flu virus from spreading inside the body. This can lead to improved symptoms of flu and quicker recovery. If you have been exposed to someone with the flu, taking RELENZA® can help keep the virus from making you sick.

What are the possible severe side effects from RELENZA®?

People should be aware of the risk of increased difficulty breathing, especially among people with a history of underlying breathing problems. If patients have increased difficulty breathing, they should stop RELENZA® and get medical attention right away. People with the flu, particularly children and adolescents, may be at an increased risk of seizures, confusion, or abnormal behavior early in their illness. These events may occur after beginning RELENZA® or may occur when flu is not treated. These events are uncommon but may result in accidental injury to the patient. Therefore, patients should be observed for signs of unusual behavior and a health care provider should be contacted immediately if the patient shows any signs of unusual behavior.

Is there an alternative treatment?

Yes. At this time, the Centers for Disease Control and Prevention (CDC) recommends the use of either RELENZA® or TAMIFLU® (oseltamivir phosphate) for the treatment and/or prevention of infection with 2009 H1N1 flu. However, RELENZA® is the only treatment that can be inhaled.

What if I decide not to treat myself or my child with RELENZA®?

It is your choice whether you or your child are treated with RELENZA®. You can decide not to take or stop taking it any time. It will not change the rest of your regular medical care.

How do I report side effects with RELENZA®?

Call your health care provider if you or your child experience side effects that bother you or your child or that do not go away. Report side effects to **FDA MedWatch** at www.fda.gov/medwatch or call 1-800-FDA-1088.

How can I learn more?

If you have questions about your treatment, please refer to <http://www.cdc.gov/h1n1flu/eua/relenza.htm>.

What if my RELENZA® is expired?

If you were given RELENZA® that shows an expired date, you should know that FDA has authorized the use of certain lots of expired RELENZA®. FDA has reviewed information from the makers of RELENZA® and found that some RELENZA® may be used past the original expiration date printed on the package. If you want to look up the lot number for your RELENZA® to see if it has been authorized for use past the original expiration date, go to <http://www.fda.gov/NewsEvents/PublicHealthFocus/ucm154962.htm>. If you have questions or want more information, please contact the public health authority or health care provider who gave you the RELENZA®.