

ZANAMIVIR SUMMARY FACT SHEET FOR PATIENTS AND PARENTS

You have been given zanamivir because you may have been exposed to the swine influenza (swine flu). As you may already be aware, a public health emergency has been declared in the U.S. due to a current outbreak of swine influenza virus. You can decide whether to take this drug. Taking zanamivir may help you or your child recover more quickly if you have swine flu or may help keep you or your child from getting sick from swine flu. If you are taking zanamivir as directed and you begin to feel sick, get medical care right away.

What is Swine Flu?

Swine flu is a respiratory disease of pigs caused by a virus that regularly causes outbreaks of influenza in pigs. Spread of swine flu can occur through contact with infected pigs or environments, or through contact with a person with swine flu.

What is Zanamivir?

Relenza[®] (zanamivir) 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 zanamivir can be found via Drugs@FDA on www.fda.gov/cder.

Who should not take Zanamivir?

Do not take zanamivir if you have ever had a severe allergic reaction to zanamivir or lactose. Zanamivir is not recommended for people with chronic lung disease such as asthma or COPD. Zanamivir 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 Zanamivir?

- **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

The dose should be given at approximately the same time each day.

How should zanamivir be taken?

Zanamivir 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 zanamivir 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 healthcare provider for instructions on how to use the Diskhaler[®]. Zanamivir should be given to children only under adult supervision and instruction.

What are the possible severe side effects from Zanamivir?

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 zanamivir 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 healthcare professional should be contacted immediately if the patient shows any signs of unusual behavior.

How do I report side effects with Zanamivir?

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

*Certain aspects of this emergency use are not part of the approved drug applications. However, the FDA Commissioner has authorized the emergency use of zanamivir. Additional information can be found on www.cdc.gov/swineflu.