

**EMERGENCY USE AUTHORIZATION of RELENZA[®]:
FACT SHEET FOR HEALTH CARE PROVIDERS¹**

You have been asked as a health care provider to give RELENZA[®] (zanamivir), as appropriate, to people for the treatment or prevention of 2009 H1N1 flu (previously known as Swine Influenza A or Swine Flu). RELENZA[®] is approved by the U.S. Food and Drug Administration (FDA) for treatment of influenza in patients 7 years of age and older who have been symptomatic for no more than 2 days, and for prophylaxis of influenza in patients 5 years of age and older. The FDA-approved package insert on RELENZA[®] can be found via Drugs@FDA on <http://www.accessdata.fda.gov/scripts/cder/drugsatfda/index.cfm>. Certain aspects of the emergency use authorization (EUA) are not part of the approved drug application. For example, the EUA authorizes the use of the drug:

- in patients who are symptomatic for more than 2 days, and
- in patients who have complicated illness requiring hospitalization.

For more information, refer to <http://www.cdc.gov/h1n1flu/eua/relenza.htm> or www.fda.gov.

Who should not take RELENZA[®]?

Patients with a history of severe allergic reaction to RELENZA[®] or lactose, or have an underlying airway disease should not take zanamivir. 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 symptom onset, and be given at approximately the same time each day.

RELENZA[®] will be supplied in the manufacturer's packaging. 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.

RELENZA[®] should be given to children only under adult supervision and instruction, and the supervising adult should first be instructed by a healthcare professional. Instructions should include a demonstration whenever possible.

Can RELENZA[®] be reconstituted in a liquid formulation or used in nebulizers or mechanical ventilators?

No. GlaxoSmithKline (GSK) and FDA have notified healthcare providers of a report of the death of a patient with influenza who received RELENZA[®] Inhalation Powder which was solubilized and administered by mechanical ventilation. RELENZA[®] Inhalation Powder is not intended to be reconstituted in any liquid formulation and is not recommended for use in any nebulizer or mechanical ventilator.

GSK is aware that RELENZA[®] Inhalation Powder is being removed from its FDA-approved packaging and dissolved in various solutions for the purpose of nebulizing zanamivir for inhalation by patients with influenza who are unable to take oral medications or unable to inhale RELENZA[®] Inhalation Powder using the Diskhaler. RELENZA[®] for nebulization has not been approved by the FDA. The safety, effectiveness, and stability of RELENZA[®] use by nebulization have not been established.

RELENZA[®] Inhalation Powder should only be used as directed in the prescribing information by using the Diskhaler device provided with the drug product. RELENZA[®] Inhalation Powder is a mixture of zanamivir

¹ In the event of an emergency, it is possible that public health officials or other volunteers might distribute RELENZA[®] products to recipients as authorized. In this fact sheet, the term "health care provider(s)" includes these individuals and is used for brevity here.

active drug substance and lactose drug carrier. This formulation is not designed or intended to be administered by nebulization. There is a risk that the lactose sugar in this formulation can obstruct proper functioning of mechanical ventilator equipment.

What are the possible serious side effects of RELENZA®?

- Some patients have had bronchospasm or serious breathing problems when they used RELENZA®. RELENZA® is not recommended for people with chronic respiratory disease such as asthma or chronic obstructive pulmonary disease.
- Patients with lung disease should have a fast-acting inhaled bronchodilator available while being treated with RELENZA®. Bronchodilators should be used prior to administration of RELENZA®.
- 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.
- RELENZA® was not effective in reducing the chance of getting the flu in two studies in nursing home patients.
- Patients should be instructed to stop taking RELENZA® if they experience signs or symptoms of an allergic reaction.

Refer to the Package Insert for more safety information.

Make available to recipients the information in the "RELENZA® Fact Sheet for Patients and Parents/Caregivers."

Reporting And Monitoring Adverse Events

Health care providers and recipients that experience adverse events or medication errors are encouraged to report to MedWatch at www.fda.gov/medwatch, by submitting a MedWatch Form 3500 (available at http://www.fda.gov/medwatch/safety/FDA-3500_fillable.pdf) or by calling 1-800-FDA-1088.

Expired RELENZA®

If you have been asked to distribute/dispense RELENZA® that is past its original labeled expiration date, please be aware that FDA has authorized the use of certain lots of expired RELENZA® during this public health emergency. This authorization of use is based on FDA's review of data submitted by the manufacturer of RELENZA®. **For any RELENZA® that is past its original labeled expiration date, you may look up the lot number at the following website to determine if FDA has authorized its use past the expiry date:**

<http://www.fda.gov/NewsEvents/PublicHealthFocus/ucm154962.htm>. **You may inform recipients to use their expired RELENZA® if it has been authorized for use beyond the original expiration date.**