

Relenza[®] (zanamivir for inhalation) Backgrounder

Relenza is an antiviral medication that can both treat influenza (flu, infection caused by influenza virus) and reduce the chance of getting flu in the community and household settings. The flu is a highly contagious and potentially fatal disease caused by influenza types A and B. While some antiviral medications only protect against influenza A, Relenza is effective against both influenza A and B. Relenza is approved for the prophylaxis and treatment of influenza in children (5 years and older for prophylaxis and treatment in the UK*) and adults.

NOTE: * 5 years and older for prophylaxis and 7 years and older for treatment in the USA

1. How does Relenza work?

Relenza is an inhaled medicine delivered as a dry powder through a device called a Diskhaler[®] to the surface of the upper respiratory tract, and may shorten the amount of time a person is sick if used within two days of onset of illness. Relenza belongs to a group of medicines called neuraminidase inhibitors. These medications attack the influenza virus itself – not just the symptoms – and prevent it from spreading inside your body.

2. Who should take Relenza?

Relenza is indicated for adult and paediatric patients, specifically:

- For treatment of influenza: Patients at least 5 years of age who have influenza symptoms that appeared within 48 hours in the UK (Note: at least 7 years of age in the US).
- For prophylaxis use: Relenza can also help reduce the chance of getting the flu in adults and children at least 5 years of age who have a higher chance of getting the flu because they spend time with someone who has the flu within 36 hours.

3. When should Relenza be used?

Relenza should be taken within 48 hours of the onset of flu symptoms in order to be effective. If an individual develops flu-like symptoms, they should immediately speak with their doctor or healthcare provider (HCP) to see if Relenza might be right for them. Typical symptoms of the flu include sudden onset of fever, cough, headache, fatigue, body aches, and sore throat.

4. How available is Relenza?

GSK invested more than €1.7 billion to expand the company's flu vaccine manufacturing capacity and increase production of Relenza. GSK has been manufacturing Relenza for the seasonal flu season and in response to the latest flu outbreak, we have increased Relenza production.

5. What is the shelf-life for Relenza?

The current Relenza shelf life is seven years.

6. Where is Relenza manufactured?

Relenza is manufactured in three locations around the world: Evreux, France; Zebulon, North Carolina, USA; and Boronia, Australia.

For more information about Relenza, including full prescribing information, visit;
www.relenza.com (for USA)
<http://emc.medicines.org.uk/document.aspx?documentId=3789> (for UK)

Important Safety Information

Relenza is not recommended for treatment or prophylaxis of influenza in individuals with underlying airways disease (such as asthma or chronic obstructive pulmonary disease).

Serious cases of bronchospasm, including fatalities, have been reported during treatment with Relenza in patient with and without underlying airways disease. Many of these cases were reported during postmarketing and causality was difficult to assess.

If use of Relenza is considered for a patient with underlying airways disease, the potential risks and benefits should be carefully weighed. Use in these patients should be done only under conditions of careful monitoring or respiratory function, close observation, and appropriate supportive care including availability of fast-acting bronchodilators.

Discontinue Relenza and initiate appropriate treatment if an allergic reaction occurs or is suspected. Patients with influenza, particularly paediatric patients, may be at an increased risk of seizures, confusion, or abnormal behaviour early in their illness. Monitor for signs of abnormal behaviour. Safety and efficacy have not been demonstrated in patients with high-risk underlying medical conditions.

Relenza has not been proven effective for prophylaxis of influenza in the nursing home setting.

Relenza is not a substitute for early influenza vaccination on an annual basis as recommended by the Centers for Disease Control's Immunization Practices Advisory Committee.

Influenza viruses change over time. Emergence of resistance mutations could decrease drug effectiveness. Other factors (for example, changes in viral virulence) might also diminish clinical benefit of antiviral drugs. Prescribers should consider available information on influenza drug susceptibility patterns and treatment effects when deciding whether to use Relenza.