

## PACKAGE LEAFLET: INFORMATION FOR THE USER



5 mg per dose, inhalation powder, pre-dispensed  
zanamivir

**Read all of this leaflet carefully before you start using this medicine.**

This medicine has been prescribed for you personally. Don't pass it to others-it may harm others, even if their symptoms seem to be the same as yours.

Keep this leaflet. You may have to read it again.

If you have any questions, ask your doctor or pharmacist.

**If you have serious side effects, or if you notice any side effects not listed in this leaflet, tell your doctor or pharmacist.**

In this leaflet:

1. What Relenza is and what it is used for
2. Before you use Relenza
3. How to use Relenza
4. When to start using Relenza
5. Possible side effects
6. How to store Relenza
7. Important things to take note
8. Further information
9. Step-by-step guide to using your Relenza Diskhaler

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### **1. What Relenza is and what it is used for**

Relenza contains zanamivir, which belongs to a group of medicines called antivirals.

**Relenza is used to treat flu** (influenza virus infection). It reduces the symptoms of flu, and helps you recover more quickly.

**Relenza is also used to prevent you from getting flu**, during a flu outbreak.

Adults and children aged 5 years or more can be treated with Relenza.

Relenza needs to be inhaled (breathed in) into the lungs, because it is poorly absorbed into the body if it is swallowed. The flu virus infects the lungs and when you inhale Relenza it works directly on the virus inside your lungs.

**Relenza is not a substitute for flu vaccination.** You still need to talk to your doctor about whether you need to be vaccinated against flu.

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### **2. Before you use Relenza**

**Don't use Relenza:**

- **if you're allergic** (hypersensitive) to zanamivir
- **if you're allergic** (hypersensitive) to lactose or milk protein

If you think this applies to you, don't use Relenza until you have checked with your doctor.

**Take special care with Relenza.**

**Don't give Relenza to children under 5 years old.**

**If you have asthma, or other problems with your lungs or your breathing**

Your doctor needs to know if you have:

- **asthma**

- **other lung disease that cause breathing problems-** for example, **emphysema, chronic obstructive pulmonary disease (COPD), or chronic bronchitis.**

➔ **Tell your doctor before you use Relenza**, so that he or she can supervise you more closely to check that your condition is being controlled.

**If you used inhaled medication** for your asthma or other breathing problem, read the next part of this leaflet - *Using Relenza with inhaled medication for breathing problems* - carefully, before you use Relenza.

#### **Using Relenza with inhaled medication for breathing problems**

- if you use inhaled medication for asthma or other breathing problem, carry on using your inhaler(s) at the usual times.
- if you have been advised to use Relenza at the same time of day as your other inhaled medication, use the other medication a few minutes before you use Relenza.
- make sure you have your fast-acting “reliever” inhaler (such as salbutamol) at hand when you use Relenza.

In very rare cases, Relenza can cause reactions including:

- **tightness of the throat and chest**
- **difficulty breathing**

If you get any of these symptoms when you use Relenza:

➔ Stop using Relenza. Use your fast-acting “reliever” inhaler to help your breathing. Get medical help immediately. Contact your doctor or the nearest hospital emergency department.

#### **Other medicines and Relenza**

Tell your doctor or pharmacist if you’re taking any other medicines, if you’ve taken any other medicines recently, or if you start taking new medicines, including medicines obtained without prescription.

If you use inhaled medication for asthma or other breathing problems, make sure you have read the advice above.

#### **If you have been advised to have a flu vaccination**

You can be vaccinated at any time, even if you’re using Relenza to prevent you from getting flu.

#### **Pregnancy and breast feeding**

There is only limited information about the safety of Relenza for pregnant women.

- ➔ **Talk to your doctor if you’re pregnant, if you could be pregnant or planning to become pregnant.**
- ➔ **If you do become pregnant during treatment with Relenza, tell your doctor. Your doctor will consider the benefit to you and the risk to your baby of being given Relenza while you’re pregnant.**
- ➔ **Breast-feeding is not recommended during treatment with Relenza.**  
It is not known whether the active ingredient of Relenza (zanamivir) can pass into breast milk. If you’re breast-feeding, you must check with your doctor before you’re given Relenza.

#### **Driving and using machines**

Relenza should not affect your ability to drive or use machines.

#### **Relenza contains lactose and milk proteins**

If you have an intolerance to lactose or any other sugars, or to milk protein:

➔ Check with your doctor that Relenza is suitable for you.

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### **3. How to use Relenza**

**For maximum benefit, Relenza should ideally be taken within 48 hours after the first symptoms of flu.**

**Always use Relenza exactly as your doctor has told you to.** Check with your doctor or pharmacist if you’re not sure.

Relenza is a powdered medicine, which you inhale into your lungs through your mouth, using the **Diskhaler** device provided. The powder is contained in blisters on a **Rotadisk** a foil disk that you load into the Diskhaler. The medicine in the Rotadisks must only be inhaled using the Diskhaler device.

➔ **Carefully follow the “Step-by-step guide to using your Relenza Diskhaler” at the end of this leaflet.**

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### **4. When to start using Relenza**

**Don't give Relenza to children under 5 years old.**

**If you have flu,** for maximum benefit, start using Relenza as soon as possible when you get flu symptoms, within 48 hours after the first symptoms.

**To prevent flu**

**If someone in your household has flu, to prevent you getting it, you should start** using Relenza as soon as possible after you have come into contact with them, within 36 hours of contact with the infected person.

**How much Relenza to use**

The amount of Relenza you use depends on whether you already have flu, or you are using Relenza to prevent flu.

**If you have flu:**

- **Adults:** the usual dose is 2 inhalations (2 blisters) twice a day for 5 days.

**To prevent flu:**

- **Adults:** the usual dose is 2 inhalations (2 blisters) once a day for 10 days. This may be increased to up to one month or for as long as your doctor tells you.

**For children under 12 years old, please use the dose as recommended by your doctor.**

**If you use more Relenza than you should**

If you accidentally use too much Relenza, it's unlikely to cause you any problems.

But if you're worried or you feel unwell, especially if you have asthma or other lung problems:

➔ **Ask your doctor for advice.**

**If you forget to take Relenza**

If you forget a dose of Relenza, take your usual dose as soon as you remember, then carry on as before. Don't use a double dose to make up for a missed dose.

➔ **If you are not sure what to do, ask your doctor for advice.**

**Don't stop using Relenza without advice**

For treating flu, it's important that you complete the full course of Relenza (normally 5 days), even if you're feeling better. Otherwise, the flu symptoms may come back. If you think you may want to stop your Relenza treatment early:

➔ **Ask your doctor for advice.**

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## **5. Possible side effects**

Like all medicines, Relenza can cause side effects, but not everyone gets them.

**Conditions you need to look out for**

**Severe allergic reactions**

These are very rare in people using Relenza. Signs include:

- **raised and itchy rash (hives)**
  - **swelling, sometimes of the face or mouth, causing difficulty in breathing**
  - **collapse**
- ➔ **Contact a doctor immediately if you get these symptoms. Stop using Relenza.**

**Serious skin reactions**

These are very rare in people using Relenza. Signs include:

- **skin rash, which may blister, and looks like small targets (central dark spots surrounded by a paler area, with a dark ring around the edge - erythema multiforme)**
  - **a widespread rash with blisters and peeling skin, particularly around the mouth, nose, eyes and genitals (Stevens-Johnson syndrome)**
  - **extensive peeling of the skin on much of the body surface (toxic epidermal necrolysis)**
- ➔ **If you notice any of these symptoms, contact a doctor immediately. Stop taking Relenza.**

**Other very rare side effects**

These affect **less than 1 in 10, 000** people using Relenza:

- **Fainting and feeling lightheaded**

If you are feeling unwell when you take Relenza you may faint or become lightheaded after inhaling Relenza.

You must sit down in a relaxed position before inhaling the dose of Relenza, and you must only hold your breath for as long as is comfortable after inhaling the dose.

- ➔ **If you are feeling unwell, you are advised to have someone with you while you are inhaling the dose of Relenza.**
- **Tightness of the throat or chest, feeling short of breath, or sudden difficulty in breathing.** If you have lung disease (such as asthma or COPD), you may need to be monitored while you're using Relenza in case you get this side effect.
- **Swelling of the face, mouth or throat**
- **Skin rash or hives** (itchy bumps on your skin).

If you notice any of these symptoms:

- ➔ **Contact a doctor urgently. Stop using Relenza.**

### **Sudden changes in behaviour, hallucination and fits**

Flu can cause sudden changes in behaviour, such as:

- confusion
- unresponsiveness
- seeing, hearing things, or feeling things that are not there (hallucinations)
- fits (seizures) which can lead to loss of consciousness.

Parents should be especially careful to watch out for these symptoms if their child or teenager has flu. These symptoms can happen whether you are taking Relenza or not. Therefore, it is not known if Relenza plays a part in causing them.

If you get any of these symptoms:

- ➔ **Contact your doctor immediately.**
- ➔ **If any of the side effects become severe or troublesome or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.**

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## **6. How to store Relenza**

Keep Relenza out of reach and sight of children.

Don't use Relenza or the Diskhaler after the expiry date which is shown on the pack.

Don't store Relenza above 30°C.

Don't dispose of medicines via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. This will help to protect the environment.

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## **7. Important things to take note**

- **Do not stop taking Relenza or change the dose without first checking with your doctor.**
- **Do not give Relenza to anyone else even when they have the same condition as you.**
- **Do not use Relenza to treat other complaints unless directed by your doctor.**

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## **8. Further information**

### **What Relenza contains**

The active substance is zanamivir. Each Rotadisk blister contains 5 mg zanamivir.

The other ingredient is lactose monohydrate (which contains milk protein).

### **What Relenza looks like and contents of the pack**

Relenza powder is contained in the four blisters on the silver coloured foil disk, called a Rotadisk. Each blister contains 5 mg of zanamivir. The medicine is inhaled through the mouth from the Rotadisk using a plastic device called a Diskhaler.

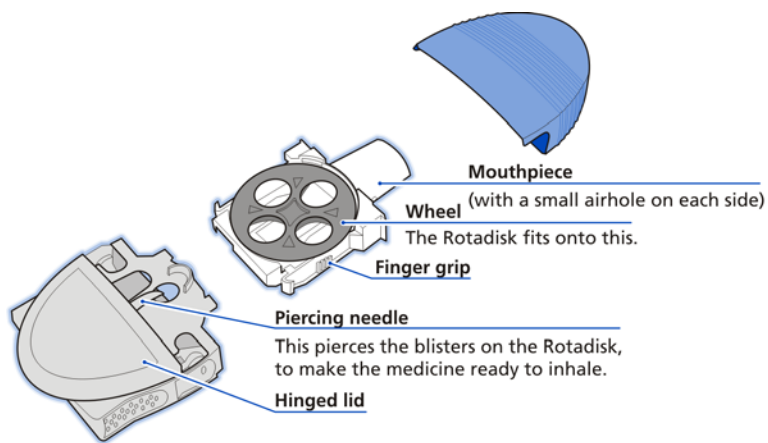
Relenza is supplied in a 5-day treatment pack containing five Relenza Rotadisks and one Diskhaler.

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## **9. Step-by-step instructions**

The Diskhaler has three parts:

Don't take it apart until you have looked at the step-by-step guide.



→ Refer to the step-by-step guide.

The Rotadisk fits into the Diskhaler.



The Rotadisk fits onto the wheel of the Diskhaler.

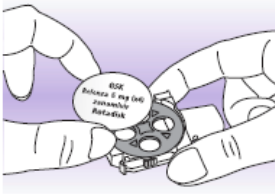
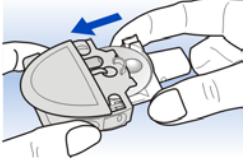
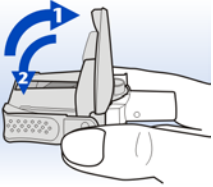

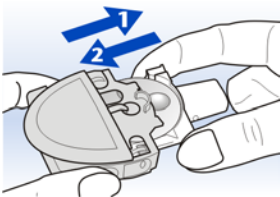
The Rotadisk contains four blisters. Each blister contains 5 mg of zanamivir. A dose is normally two blisters (10 mg).

#### Important:

- **Don't pierce any of the blisters on the Rotadisk before you load it onto the Diskhaler.**
- **You can keep a Rotadisk on the Diskhaler between doses, but don't pierce a blister until just before you inhale your dose.**
- **Keep the Diskhaler clean. Wipe the mouthpiece with a tissue after you use it, and replace the blue cover between uses.**

#### Step-by-step guide to using your Relenza Diskhaler

To load a Rotadisk into the Diskhaler:	
<b>1 Remove the blue cover.</b> Check that the mouthpiece is clean, inside and outside.	
<b>2 Hold the white sliding tray as shown and pull it out until it stops.</b>	
<b>3 Gently squeeze the finger grips on the sides of the white tray.</b> <b>Remove the tray from the main body.</b> The white tray should come out easily.	

<p><b>4 Place a new Relenza Rotadisk on the wheel.</b></p> <p>Make sure the printed side is up, with the blisters facing downwards.</p> <p>The blisters fit into the holes in the wheel.</p>	
<p><b>5 Push the white tray back into the main body.</b></p> <p><b>If you're not ready to inhale a dose of Relenza straight away, replace the blue cover.</b></p>	
<p><b>To get your dose ready to inhale:</b></p> <p><b>Don't do this until just before you inhale a dose.</b></p>	
<p><b>6 Hold the Diskhaler horizontally.</b></p> <p><b>Flip the lid up as far as it will go.</b></p> <p>The lid must be fully vertical, to make sure that the blister is pierced at both the top and bottom.</p> <p><b>Push the lid back down.</b></p> <p>Your Diskhaler is now ready for use. Keep it horizontal until you have inhaled your dose.</p>	 <p>Keep the Diskhaler horizontal</p>
<p><b>To inhale the medication:</b></p>	
<p><b>7 Sit down in a comfortable position. Don't put the Diskhaler into your mouth yet. Breathe out as far as is comfortable,</b> keeping the Diskhaler away from your mouth. <b>Don't blow into the Diskhaler.</b> If you do, you'll blow the powder out of the Rotadisk.</p> <p><b>Place the mouthpiece between your teeth. Close your lips firmly around the mouthpiece.</b></p> <p>Don't bite the mouthpiece. Don't block the airholes on the side of the mouthpiece.</p> <p><b>Take one quick, deep breath in through the mouthpiece.</b> Hold this breath for a few seconds or as long as is comfortable.</p>	 <p>Keep the Diskhaler horizontal</p>
<p><b>To prepare the next blister (the second part of your dose):</b></p>	
<p><b>8 Pull the white tray out as far as it will go (don't remove it completely), then push it back in again.</b></p> <p>This will turn the wheel so the next blister will appear.</p> <p>Repeat if necessary until a full blister is positioned under the piercing needle.</p> <p>Repeat steps <b>6</b> and <b>7</b> to inhale the medicine.</p>	

<p><b>9</b> After you've inhaled the full dose (normally two blisters):</p> <p><b>Wipe the mouthpiece with a tissue and replace the blue cover.</b> It's important to keep the Diskhaler clean.</p>	
<p><b>To replace the Rotadisk:</b></p>	
<p><b>10</b> When all four blisters are empty, remove the Rotadisk from the Diskhaler and insert a new one, using steps <b>1</b> to <b>5</b>.</p>	

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