
Package Leaflet: Information for the User

RELENZA

5 mg per dose, inhalation powder, pre-dispensed

zanamivir

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, pharmacist or nurse.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

- 1 **What Relenza is and what it is used for**
- 2 **What you need to know before you use Relenza**
- 3 **How to use Relenza**
- 4 **Possible side effects**
- 5 **How to store Relenza**
- 6 **Contents of the pack and other information**

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 help 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.

2 **What you need to know before you use Relenza**

Do not use Relenza

- **if you are allergic** to zanamivir or any of the other ingredients of this medicine (listed in section 6).
- **if you have a milk protein allergy** (see 'Relenza contains lactose and milk protein' and section 6)

Do not give Relenza to children under 5 years old.

Take special care with Relenza

If you feel tightness in your throat or chest when you use Relenza

In very rare cases, Relenza can cause a reaction including:

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

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

→ **Stop using Relenza and get medical help immediately.** Contact your doctor or the nearest hospital emergency department.

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 causes 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 use 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 any 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) to hand when you use Relenza.

Other medicines and Relenza

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, including medicines obtained without a 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 are using Relenza to help prevent you from getting flu.

Pregnancy, breast-feeding and fertility

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask

→ **your doctor for advice before taking this medicine.**

There is only limited information about the safety of Relenza for pregnant women. Although there is no evidence so far that Relenza harms unborn babies, you should not use it during pregnancy unless your doctor has advised you to.

The active ingredient (zanamivir) could get into breast milk, therefore you should not breast-feed while taking Relenza. You should discuss with your doctor whether you should stop or abstain from taking Relenza or stop breast-feeding, depending on what is best for you and your baby.

Driving and using machines

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

Relenza contains lactose and milk protein

Relenza contains a sugar called lactose, and contains milk protein.

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

3 How to use Relenza

Always use this medicine exactly as your doctor or pharmacist has told you to. Check with your doctor or pharmacist if you are not sure.

Relenza is a powdered medicine, which you inhale into your lungs through your mouth, using the **Diskhaler** device. The powder is contained in blisters on a **Rotadisk** — a foil disk which you load into the Diskhaler.

The medicine in the Rotadisks must only be inhaled using the Diskhaler device.

Do not give Relenza to children under 5 years old.

When to start using Relenza

If you have flu, for maximum benefit, you should start using Relenza as soon as possible when you get flu symptoms:

- **for adults, within 48 hours** after the first symptoms
- **for children, within 36 hours** after the first symptoms.

To help prevent flu

If someone in your household has flu, to help prevent you getting it, you should start using Relenza as soon as possible after you have come into contact with them:

- **For adults and children, within 36 hours** of contact with the infected person.

If there is a flu outbreak in your local community, follow your doctor's advice on when to start using Relenza.

How much Relenza to use

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

If you have flu:

- **Adults and children (aged 5 years or more):** the usual dose is 2 inhalations (2 blisters) twice a day for 5 days.

To help prevent flu:

- **If someone in your household has flu:**
Adults and children (aged 5 years or more): the usual dose is 2 inhalations (2 blisters) once a day for 10 days.

If there is a flu outbreak in your local community:

- **Adults and children (aged 5 years or more):** the recommended dose is 2 inhalations (2 blisters) once a day for up to 28 days

If you use more Relenza than you should

If you accidentally use too much Relenza, it is unlikely to cause you problems.

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

→ **Ask your doctor for advice.**

If you forget to use Relenza

If you forget a dose of Relenza, take your usual dose as soon as you remember, then carry on as before.

Do not use a double dose to make up for a forgotten dose.

If you stop using Relenza

For treating flu, it is important that you complete the full course of treatment (normally 5 days), even if you are 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.**

There is a step-by-step guide on the other side of this leaflet, showing you how to use the Relenza Diskhaler.

Read it carefully before you use your first dose. If you are still not sure how to use the Diskhaler, ask your pharmacist to go through the instructions with you.

4 Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.
Conditions you need to look out for:

Severe allergic reactions

These are rare and affect **less than 1 in 1,000** people using Relenza. Signs include:

Raised and itchy rash (hives).

Swelling, sometimes of the face, mouth or throat, causing difficulty in breathing.
Collapse.

If you get any of these symptoms:

- **Contact your doctor immediately.**

Serious skin reactions

These side effects are rare and may affect **less than 1 in 1,000** people using Relenza:

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 using Relenza.

Other common side effects

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

Skin rash

Other uncommon side effects

These affect **less than 1 in 100** people using 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 are using Relenza in case you get this side effect.

Swelling of the face, mouth or throat

Hives (itchy bumps on your skin).

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.

If you get any of these effects:

→ **Stop using Relenza and get medical help immediately.** Contact your doctor or the nearest hospital emergency department.

Sudden changes in behaviour, hallucinations and fits

During treatment with Relenza, changes in behaviour such as confusion and unresponsiveness have occurred. Some people may also have hallucinations (seeing, hearing, or feeling things not there) or 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 have been seen in people with flu who were not taking Relenza. Therefore it is not known if Relenza played a part in causing them.

If you get any of these symptoms:
→ Contact your doctor immediately.

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via HPRA Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: www.hpra.ie; E-mail: medsafety@hpra.ie. By reporting side effects you can help provide more information on the safety of this medicine.

5 How to store Relenza

Keep this medicine out of the sight and reach of children.
Do not use Relenza or the Diskhaler after the expiry date (EXP) which is stated on the pack.
Do not store Relenza above 30 °C.
Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

Ask your pharmacist how to throw away the Diskhaler you no longer use. These measures will help protect the environment.

6 Contents of the pack and other information

What Relenza contains

The active substance is zanamivir (5 mg per dose).
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 aluminium 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 two types of pack:

- a **1-day starter pack** containing one Relenza Rotadisk and one Diskhaler
- a **5-day treatment pack** containing five Relenza Rotadisks and one Diskhaler

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder:

GlaxoSmithKline (Ireland) Ltd., 12 Riverwalk, Citywest Business Campus, Dublin 24, Ireland

Manufacturer:

GlaxoSmithKline Trading Services Limited, 12 Riverwalk, Citywest Business Campus, Dublin 24, Ireland

Glaxo Wellcome Production, Zone Industrielle No.2, 23 Rue Lavoisier, 27000 Evreux, France

Manufacturer for Diskhaler:

GlaxoSmithKline Trading Services Limited, 12 Riverwalk, Citywest Business Campus, Dublin 24, Ireland

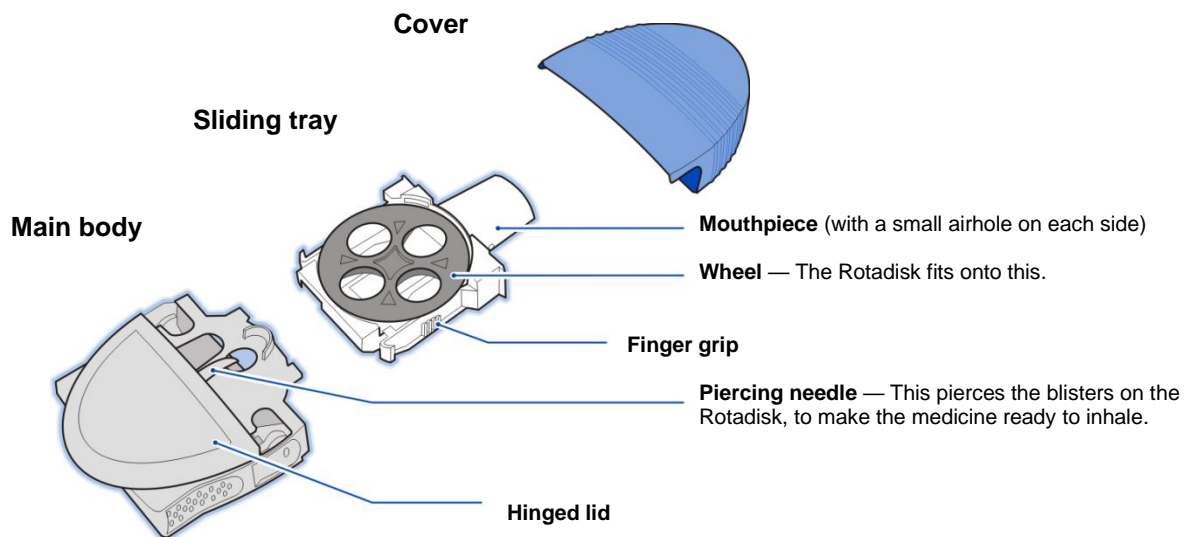
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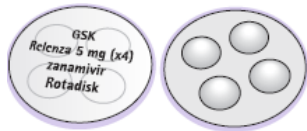
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The Diskhaler has three parts:

Do not take it apart until you have looked at 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).

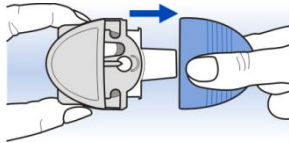
Important:

- **Do not 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 **do not 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.
- **Tell your doctor or pharmacist of any malfunction or problems with the Diskhaler and Rotadisk.**

Step-by-step guide to using your Relenza Diskhaler

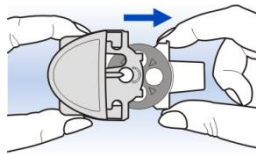
To load a Rotadisk into the Diskhaler:

- 1 **Remove the blue cover.**

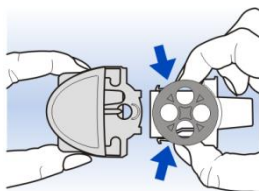


Check that the mouthpiece is clean, inside and outside.

- 2 **Hold the white sliding tray as shown and pull it out until it stops.**

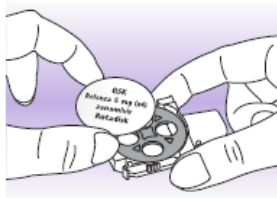


- 3 **Gently squeeze the finger grips on the sides of the white tray. Remove the tray from the main body.**



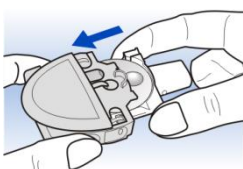
The white tray should come out easily.

- 4 **Place a new Relenza Rotadisk on the wheel.**



Make sure the printed side is up, with the blisters facing downwards.
The blisters fit into the holes in the wheel.

- 5 **Push the white tray back into the main body.**

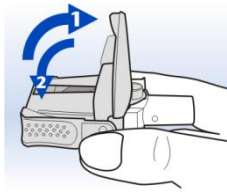


If you are not ready to inhale a dose of Relenza straight away, replace the blue cover.

To get your dose ready to inhale:

Do not do this until just before you inhale a dose.

6 Hold the Diskhaler horizontally.



Keep the Diskhaler horizontal

Flip the lid up as far as it will go.

The lid must be fully vertical, to make sure that the blister is pierced at both the top and bottom.

Push the lid back down.

Your Diskhaler is now ready for use. Keep it horizontal until you have inhaled your dose.

If you use other inhaled medication, make sure you read '*Using Relenza with inhaled medication for breathing problems*' in Section 2 of this leaflet.

To inhale the medication:

7 Do not put the Diskhaler into your mouth yet.

Breathe out as far as is comfortable, keeping the Diskhaler away from your mouth. **Do not blow into the Diskhaler.** If you do, you will blow the powder out of the Rotadisk.



Keep the Diskhaler horizontal

Place the mouthpiece between your teeth. Close your lips firmly around the mouthpiece.

Do not bite the mouthpiece. Do not block the airholes on the side of the mouthpiece.

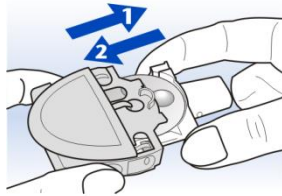
Take one quick, deep breath in through the mouthpiece. Hold this breath for a few seconds.

Remove the Diskhaler from your mouth.

Carry on holding your breath for a few more seconds or as long as is comfortable

To prepare the next blister (the second part of your dose):

- 8** Pull the white tray out as far as it will go (do not remove it completely), then push it back in again.



This will turn the wheel so the next blister will appear.

Repeat if necessary until a full blister is positioned under the piercing needle.

Repeat steps **6** and **7** to inhale the medicine.

- 9** After you have inhaled the full dose (normally two blisters):

Wipe the mouthpiece with a tissue and replace the blue cover. It is important to keep the Diskhaler clean.

To replace the Rotadisk:

- 10** When all four blisters are empty, remove the Rotadisk from the Diskhaler and insert a new one, using steps **1** to **5**.