

**PARTICULARS TO APPEAR ON THE OUTER PACKAGING AND THE IMMEDIATE PACKAGING**

**OUTER CARTON**

**1. NAME OF THE MEDICINAL PRODUCT**

Relenza 5 mg/dose, inhalation powder, pre-dispensed.

Zanamivir

**2. STATEMENT OF ACTIVE SUBSTANCE(S)**

Each blister contains zanamivir 5 mg.

**3. LIST OF EXCIPIENTS**

Lactose monohydrate (which contains milk proteins)

**4. PHARMACEUTICAL FORM AND CONTENTS**

Inhalation powder, pre-dispensed

1 Diskhaler

5 Rotadisks (4 blisters per Rotadisk)

1 Rotadisk (4 blisters)

**5. METHOD AND ROUTE(S) OF ADMINISTRATION**

Inhalation use

Read the package leaflet before use.

**6. SPECIAL WARNING THAT THE MEDICINAL PRODUCT MUST BE STORED OUT OF THE SIGHT AND REACH OF CHILDREN**

Keep out of the sight and reach of children.

**7. OTHER SPECIAL WARNING(S), IF NECESSARY**

**8. EXPIRY DATE**

EXP {MM/YYYY}

**9. SPECIAL STORAGE CONDITIONS**

Do not store above 30°C

**10. SPECIAL PRECAUTIONS FOR DISPOSAL OF UNUSED MEDICINAL PRODUCTS OR WASTE MATERIALS DERIVED FROM SUCH MEDICINAL PRODUCTS, IF APPROPRIATE**

**11. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER**

<[To be completed nationally]>

**12. MARKETING AUTHORISATION NUMBER(S)**

<[To be completed nationally]>

**13. BATCH NUMBER**

LOT

**14. GENERAL CLASSIFICATION FOR SUPPLY**

Medicinal product subject to medical prescription.

**15. INSTRUCTIONS ON USE**

**16. INFORMATION IN BRAILLE**

<[To be completed nationally]>

**17. UNIQUE IDENTIFIER – 2D BARCODE**

2D barcode carrying the unique identifier included

**18. UNIQUE IDENTIFIER – HUMAN READABLE DATA**

PC:  
SN:  
NN:

**PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGING**

**ROTADISK TUB**

**1. NAME OF THE MEDICINAL PRODUCT**

Relenza 5 mg/dose, inhalation powder, pre-dispensed.

Zanamivir

**2. STATEMENT OF ACTIVE SUBSTANCE(S)**

Each blister contains zanamivir 5 mg.

**3. LIST OF EXCIPIENTS**

Lactose monohydrate (which contains milk proteins)

**4. PHARMACEUTICAL FORM AND CONTENTS**

Inhalation powder, pre-dispensed

5 Rotadisks (4 blisters per Rotadisk)

1 Rotadisk (4 blisters)

**5. METHOD AND ROUTE(S) OF ADMINISTRATION**

Inhalation use

Read the package leaflet before use.

**6. SPECIAL WARNING THAT THE MEDICINAL PRODUCT MUST BE STORED OUT OF THE SIGHT AND REACH OF CHILDREN**

Keep out of the sight and reach of children.

**7. OTHER SPECIAL WARNING(S), IF NECESSARY**

**8. EXPIRY DATE**

EXP {MM/YYYY}

**9. SPECIAL STORAGE CONDITIONS**

Do not store above 30°C

**10. SPECIAL PRECAUTIONS FOR DISPOSAL OF UNUSED MEDICINAL PRODUCTS OR WASTE MATERIALS DERIVED FROM SUCH MEDICINAL PRODUCTS, IF APPROPRIATE**

<b>11. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER</b>
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<[To be completed nationally]>

<b>12. MARKETING AUTHORISATION NUMBER(S)</b>
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<[To be completed nationally]>

<b>13. BATCH NUMBER</b>
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LOT

<b>14. GENERAL CLASSIFICATION FOR SUPPLY</b>
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Medicinal product subject to medical prescription.

<b>15. INSTRUCTIONS ON USE</b>
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<b>16. INFORMATION IN BRAILLE</b>
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<[To be completed nationally]>

<b>17. UNIQUE IDENTIFIER – 2D BARCODE</b>
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<b>18. UNIQUE IDENTIFIER – HUMAN READABLE DATA</b>
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**MINIMUM PARTICULARS TO APPEAR ON BLISTERS OR STRIPS**

**ROTADISK**

**1. NAME OF THE MEDICINAL PRODUCT**

Relenza 5 mg (x4)

zanamivir

Rotadisk

**2. NAME OF THE MARKETING AUTHORISATION HOLDER**

<[To be completed nationally]>

**3. EXPIRY DATE**

EXP

**4. BATCH NUMBER**

LOT

**5. OTHER**

<b>MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS</b> <b>DISKHALER LABEL</b>
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<b>1. NAME OF THE MEDICINAL PRODUCT AND ROUTE(S) OF ADMINISTRATION</b>
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RELENZA

Diskhaler

GlaxoSmithKline

<b>2. METHOD OF ADMINISTRATION</b>
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<b>3. EXPIRY DATE</b>
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<b>4. BATCH NUMBER</b>
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<b>5. CONTENTS BY WEIGHT, BY VOLUME OR BY UNIT</b>
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<b>6. OTHER</b>
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**RELENZA**  
5 mg per dose, inhalation powder, prepackaged

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**

- What Relenza is and what it is used for
- What you need to know before you use Relenza
- How to use Relenza
- Possible side effects
- How to store Relenza
- 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. It helps to stop the flu virus (influenza virus) from multiplying. 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 affects the lungs, and when you inhale Relenza it works directly on the virus inside your lungs.

Relenza is not a vaccine 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 5.
- If you have a milk protein allergy (see Relenza contains lactose and milk protein) and section 5).

Do not give Relenza to children under 5 years old.

**Take special care with Relenza**

If you have tightness in your throat or chest when you use Relenza:

- In very rare cases, Relenza can cause a reaction including:
  - tightness of the throat or 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:

- 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 inhaled 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.

**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 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.

**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.

**4 Possible side effects**

Like all medicines, this medicine can cause side effects, although not everyone 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:

- Rashes and itchy rash (hives).

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

**Coughs.**

**If you get any of these symptoms:**

- Stop using Relenza 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 blisters. Central dark spots surrounded by a pale 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 genital (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 dizzy.

If you are feeling unwell when you take Relenza you may faint or become light-headed after taking 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 UKRA Pharmacovigilance, Ladbroke Grove, 811, (Dorset 2), Tel: +353 1 6060711, Fax: +353 1 6060717, Web: [www.ukra.ie](http://www.ukra.ie), e-mail: [pspharmacovigilance@ukra.ie](mailto:pspharmacovigilance@ukra.ie)

If you report side effects you can help provide more information on the safety of this medicine.

**6 Contents of the pack and other information**

**What Relenza contains**

The active substance is zanamivir (5 mg per dose). The other ingredients are 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 packs:

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

Not all pack sizes may be marketed.

**Marketing Authorisation Holder and Manufacturer**

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

**Manufacturer for Diskhaler:**

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

**Manufacturer for Diskhaler:**

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

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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 place 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 place 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.
- For your doctor or pharmacist or 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:**

- Remove the blue cover. Check that the mouthpiece is clean, inside and outside.
- Hold the white sliding tray as shown and push it out until it stops.
- 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.
- 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.

- Hold the Diskhaler non-vertically. Flip the lid up as far as it will go. The lid must be fully vertical, to make sure that the piercing needle 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:**

- 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. 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 mouth for a few more seconds or as long as is comfortable.
- Prepare the next blister (the second part of your dose): Push 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.
- 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: When all four blisters are empty, remove the Rotadisk from the Diskhaler and insert a new one, using steps 1 to 5.

Keep the Diskhaler horizontal