

RELENZA ROTADISKS

Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

1. Why am I using RELENZA?

RELENZA contains the active ingredient zanamivir. RELENZA is used to treat Influenza, which is a specific viral infection.

For more information, see Section [1. Why am I using RELENZA?](#) in the full CMI.

2. What should I know before I use RELENZA?

Do not use if you have ever had an allergic reaction to RELENZA or any of the ingredients listed at the end of the CMI.

Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.

For more information, see Section [2. What should I know before I use RELENZA?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with RELENZA and affect how it works.

A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

4. How do I use RELENZA?

- For the treatment of influenza, you should breathe in the contents of two blisters, twice a day (usually morning and evening), for five days.
- For the prevention of influenza, breathe in the contents of two blisters once a day only.

More instructions can be found in Section [4. How do I use RELENZA?](#) in the full CMI.

5. What should I know while using RELENZA?

Things you should do	<ul style="list-style-type: none">• Remind any doctor, dentist or pharmacist you visit that you are using RELENZA.
Things you should not do	<ul style="list-style-type: none">• Do not stop taking RELENZA, or change

	<p>the dose, without first checking with your doctor</p> <ul style="list-style-type: none"> • Do not give this medicine to anyone else, even if their symptoms seem similar to yours • Do not use RELENZA to treat any other complaints
Driving or using machines	<ul style="list-style-type: none"> • Be careful before you drive or use any machines or tools until you know how RELENZA ROTADISKS affects you.
Looking after your medicine	<ul style="list-style-type: none"> • Store below 30°C • Store in original packaging

For more information, see Section [5. What should I know while using?](#) in the full CMI.

6. Are there any side effects?

Side effects that have been reported include feeling lightheaded and fainting. Serious side effects include allergic reaction, shortness of breath, wheezing, skin rash which may blister, a widespread rash with blisters

and peeling skin, and extensive peeling of the skin on much of the body surface.

For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

RELENZA ROTADISKS

Active ingredient(s): *zanamivir*

Consumer Medicine Information (CMI)

This leaflet provides important information about using RELENZA ROTADISKS (hereafter referred to as RELENZA). **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using RELENZA.**

Where to find information in this leaflet:

- [1. Why am I using RELENZA?](#)
- [2. What should I know before I use RELENZA?](#)
- [3. What if I am taking other medicines?](#)
- [4. How do I use RELENZA?](#)
- [5. What should I know while using RELENZA?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

1. Why am I using RELENZA?

RELENZA contains the active ingredient zanamivir 5mg.

RELENZA is an antiviral.

RELENZA is used to treat Influenza, which is a specific viral infection.

RELENZA may be given to prevent infection due to influenza in circumstances where prophylaxis is justified (eg when no suitable vaccine is available for the circulating influenza or when there is a pandemic). It is not recommended for routine prophylaxis against influenza infection.

Using a DISKHALER, RELENZA is delivered directly to the primary site of infection in the lungs. It works by destroying a chemical on the surface of the influenza virus. This stops the virus multiplying and spreading throughout the nose, lungs and air passages. However, vaccination remains the primary method of preventing and controlling influenza.

RELENZA does not work for the common cold or virus infections other than influenza.

Best results are obtained by taking RELENZA as soon as possible after developing symptoms.

2. What should I know before I use RELENZA?

Warnings

Do not use RELENZA if:

- you are allergic to zanamivir, or any of the ingredients listed at the end of this leaflet. Always check the ingredients to make sure you can use this medicine
- you have ever had a severe intolerance to lactose or any other sugars, or to milk protein

Check with your doctor if you:

- have any other medical conditions
 - asthma or other breathing problems, or if you normally use an asthma inhaler
- take any medicines for any other condition

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section [6. Are there any side effects?](#)

Pregnancy and breastfeeding

Do not take RELENZA if you are breastfeeding, pregnant or trying to become pregnant, unless your doctor says you should.

Children

There is no information on the use of RELENZA in children less than 5 years. The same dose is recommended in children between 5 and 12 years of age, as in adults. An adult should supervise the use of the delivery device when RELENZA is given to children.

Elderly

There is limited experience with the use of RELENZA in elderly patients (65 years and older). The same dose is recommended in elderly patients.

Patients with asthma

There is a risk RELENZA could cause increased difficulty with breathing, especially if you have asthma or other breathing problems.

If you have asthma or breathing problems such as wheezing or shortness of breath which gets worse while taking RELENZA you should stop taking it and contact your physician.

If you have asthma or breathing problems and take RELENZA you should have a fast-acting bronchodilator available. If you are to take inhaled bronchodilators at the same time as RELENZA you should use the bronchodilator before taking RELENZA.

3. What if I am taking other medicines?

Tell your doctor or pharmacist if you are taking any other medicines, including any medicines, vitamins or supplements that you buy without a prescription from your pharmacy, supermarket or health food shop.

Some medicines may interfere with RELENZA and affect how it works.

- RELENZA is unlikely to be affected by other drugs taken for influenza (for example, paracetamol or cough medicine).

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect RELENZA.

4. How do I use RELENZA?

How much to take

Treatment of influenza

- breathe in the contents of two blisters, twice a day (usually morning and evening), for five days

Prevention of influenza

- breathe in the contents of two blisters once a day only

When to take RELENZA

- other inhaled drugs e.g. inhaled asthma medication which is due to be taken at approximately the same time as RELENZA should be taken before taking RELENZA
- follow the instructions provided and use RELENZA until your doctor tells you to stop

Treatment of influenza

- start taking RELENZA as soon as possible but no later than forty-eight hours after developing symptoms to get the best effect

Prevention of influenza

- start taking RELENZA as soon as possible after an outbreak is declared, or after coming into contact with someone who has contracted influenza.

How to take RELENZA via diskhaler

- RELENZA comes as a fine powder. This powder is in small pockets (known as blisters) in a round foil sheet, known as a disk
- the medicine in your RELENZA disk is taken by breathing it in through your mouth using only the RELENZA DISKHALER.
- place the Disk in the DISKHALER device and breathe the powder in through your mouth following the instruction sheet that is in the box containing your DISKHALER.
- sit in a relaxed position and do not hold your breath longer than is comfortable after inhaling the dose.

If you forget to use RELENZA

Take it as soon as you remember, then go back to taking it as you would normally. If it is almost time for your next dose, skip the dose you missed and take your next dose when you are meant to.

Do not take a double dose to make up for the dose you missed.

If you use too much RELENZA

If you think that you have used too much RELENZA, you may need urgent medical attention.

You should immediately:

- phone the Poisons Information Centre (**by calling 13 11 26**), or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

You should do this even if there are no signs of discomfort or poisoning.

5. What should I know while using RELENZA?

Things you should do

If you have a reliever inhaler to use for asthma or other breathing problems make sure the inhaler is available, as very rarely you may need to use it after using RELENZA.

Have someone with you while you are inhaling the dose of RELENZA.

Call your doctor straight away if you:

- show any signs of unusual behaviour. People with influenza, particularly children and adolescents,

may be at an increased risk of seizures, confusion, or abnormal behaviour early in their illness. These events may occur after beginning RELENZA or may occur when influenza is not treated. These events are uncommon but may result in accidental injury to the patient.

Remind any doctor, dentist or pharmacist you visit that you are using RELENZA.

Things you should not do

- do not miss any doses
- do not stop taking RELENZA, or change the dose, without first checking with your doctor
- do not give this medicine to anyone else, even if their symptoms seem similar to yours
- do not use RELENZA to treat any other complaints

Driving or using machines

Be careful before you drive or use any machines or tools until you know how RELENZA affects you.

Looking after your medicine

- store below 30°C
- store in original packaging

Follow the instructions in the carton on how to take care of your medicine properly.

Store it in a cool dry place away from moisture, heat or sunlight; for example, do not store it:

- in the bathroom or near a sink, or
- in the car or on window sills.

Keep it where young children cannot reach it.

Getting rid of any unwanted medicine

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

Do not use this medicine after the expiry date or if the packaging is torn or shows signs of tampering.

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

Less serious side effects

Less serious side effects	What to do
General disorders and administration site conditions: <ul style="list-style-type: none"> • feeling lightheaded or fainting 	<p>Speak to your doctor if you have any of these less serious side effects and they worry you.</p> <p>To avoid feeling lightheaded or fainting following RELENZA</p>

Less serious side effects	What to do
	<p>treatment, sit in a relaxed position and do not hold your breath longer than is comfortable after inhaling the dose.</p> <p>If you are feeling unwell when you take RELENZA you may faint or become lightheaded after inhaling RELENZA. You are therefore advised to have someone with you while you are inhaling the dose of RELENZA.</p>

Serious side effects

Serious side effects	What to do
<p>Immune system disorders and allergic reactions:</p> <ul style="list-style-type: none"> • wheezing • swelling of the lips/ mouth/face • difficulty in breathing • hay fever 	<p>Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.</p>

Serious side effects	What to do
<ul style="list-style-type: none"> • lumpy rash ("hives") • collapse • fainting <p>Respiratory, thoracic and mediastinal disorders</p> <ul style="list-style-type: none"> • shortness of breath • wheezing <p>Skin and subcutaneous tissue disorders</p> <ul style="list-style-type: none"> • skin rash which may blister • a widespread rash with blisters and peeling skin, • extensive peeling of the skin on much of the body surface. 	

Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.

Other side effects not listed here may occur in some people.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems. By reporting side

effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

This medicine is only available with a doctor's prescription.

What RELENZA contains

Active ingredient (main ingredient)	zanamivir
Other ingredients (inactive ingredients)	lactose monohydrate
Potential allergens	Contains lactose (milk protein) Does not contain gluten

Do not take this medicine if you are allergic to any of these ingredients.

What RELENZA looks like

RELENZA is a fine powder packed in small "blisters" on a circular foil Disk. Each Disk has four blisters containing 5 mg of zanamivir and 20 mg of lactose monohydrate.

Each pack contains five Disks (AUST R 66962).

Who distributes RELENZA ROTADISKS

GlaxoSmithKline Australia Pty Ltd

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Abbotsford, Victoria, 3067

Phone: 1800 033 109

www.gsk.com.au

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