

RELENZA ROTADISKS

zanamivir 5 mg insufflation blister packs

Consumer Medicine Information

What is in this leaflet?

Please read this leaflet carefully before you start RELENZA ROTADISKS (hereafter referred to as RELENZA).

This leaflet answers some common questions about RELENZA. It does not contain all of the available information.

It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the expected benefits of you taking RELENZA against the risks this medicine could have for you.

If you have any concerns about taking this medicine, ask your doctor or pharmacist.

Keep this leaflet with the medicine.

You may need to read it again.

What is RELENZA used for

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

RELENZA can be used to prevent symptoms and illness due to influenza infection. However, vaccination remains the primary method of preventing and controlling influenza. 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.

RELENZA contains zanamivir and is available only with a doctor's prescription.

Using a DISKHALER device, 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.

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

For the prevention of influenza, it should be taken as soon as possible after an outbreak is declared, or after coming into contact with someone who has contracted influenza.

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

Ask your doctor if you have any questions about why RELENZA has been prescribed for you.

Use in children and elderly patients

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.

There is limited experience with the use of RELENZA in elderly patients

(65 years and older). The same dose is recommended in elderly patients.

Before you take RELENZA

When you must not take it

- Do not take RELENZA if you have ever had an allergic reaction to zanamivir or any of the other ingredients in this medicine (listed at the end of this leaflet).
- Do not take RELENZA if you have ever had a severe intolerance to lactose or any other sugars, or to milk protein.
- Do not take RELENZA if you are breastfeeding, pregnant or trying to become pregnant, unless your doctor says you should.

You should discuss any concerns you have with your doctor.

- Do not take RELENZA after the expiry date (EXP) printed on the pack.
- Do not take RELENZA if the packaging is torn or shows signs of tampering.
- If you suffer from asthma or other breathing problems, or if you normally use an asthma inhaler, you should discuss the use of RELENZA with your doctor.

If you're not sure whether you should be taking RELENZA, talk to your doctor.

There is a risk that 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 get 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.

- **Tell your doctor if you are allergic to any foods or medicines or if you are taking any other medicines.**

Some medicines may affect the way others work. RELENZA is unlikely to be affected by other drugs taken for influenza (for example, paracetamol or cough medicine).

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. Therefore, patients should be observed for signs of unusual behaviour and contact your doctor immediately if the patient shows any signs of unusual behaviour.

How to take RELENZA

The Pharmacist's label on the pack will tell you how to take your RELENZA. If there is something you do not understand, ask your doctor or pharmacist.

To treat influenza, you should start taking RELENZA as soon as possible but no later than forty-eight hours after developing symptoms to get the best effect.

Note: 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.

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.

How much to take

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. Follow the instruction sheet that is in the box containing your DISKHALER.

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.

Do not miss any doses.

Note: 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.

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.

If you forget to take a dose

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 that you missed.

If you take too much (overdose)

Immediately telephone your doctor or Poisons Information Centre (telephone 131126) for advice, if you think you or anyone else may have taken too much RELENZA, even if there are no signs of discomfort or poisoning.

If you are not sure what to do, contact your doctor or pharmacist.

While you are taking RELENZA

Things you must do

If you are about to be started on any other medication, tell your doctor or pharmacist that you are taking RELENZA.

Things you must not do

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.

Things to be careful of

Be careful driving or operating machinery until you know how RELENZA affects you.

Side-Effects

Check with your doctor as soon as possible if you have any problems while taking RELENZA, even if you do not think the problem is related to the medicine.

Most people taking RELENZA find that it causes no problems.

However, very rarely, some people have experienced:

- shortness of breath

- wheezing
- swelling of the face or in the mouth or throat
- an itchy, raised skin rash (hives)
- skin rash which may blister
- a widespread rash with blisters and peeling skin,
- extensive peeling of the skin on much of the body surface.
- fainting and feeling lightheaded.

To avoid feeling lightheaded or fainting following RELENZA treatment, sit in a relaxed position and do not hold your breath longer than is comfortable after inhaling the dose.

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.

If this occurs stop taking RELENZA and contact your doctor immediately. Many but not all of these patients who had breathing problems had previous asthma or chronic obstructive pulmonary disease.

If you feel you are experiencing a side-effect, talk to your doctor or pharmacist. There may be some side-effects which are not yet known.

If you think you are having an allergic reaction to RELENZA, TELL YOUR DOCTOR IMMEDIATELY or go to the Accident and Emergency department at your nearest hospital. Symptoms usually include some or all of the following:

- wheezing
- swelling of the lips/mouth/face
- difficulty in breathing
- hay fever
- lumpy rash ("hives")
- collapse
- fainting

Discuss any concerns you may have regarding RELENZA with your doctor or pharmacist.

Storage

Keep this medicine where children cannot reach it.

Keep RELENZA in a cool, dry place where the temperature stays below 30°C.

Product description

What it looks like

RELENZA is a fine powder packed in small "blisters" on a circular foil Disk. Each Disk has four blisters.

Each pack contains five Disks.

Place the Disk in the DISKHALER device and breathe the powder in through your mouth following the instructions provided in the DISKHALER leaflet.

Ingredients

RELENZA contains zanamivir (5 mg) and lactose monohydrate (20 mg). The lactose contains milk protein).

RELENZA does not contain gluten.

Further Information

Your doctor or pharmacist is the best person to give you advice on the treatment of your condition. You may also be able to find general information about your illness and its treatment from other sources, for example from books in public libraries.

Supplier

GlaxoSmithKline Australia Pty Ltd

Level 4, 436 Johnston Street
Abbotsford, Victoria, 3067

Australia

Trade marks are owned by or licensed to the GSK group of companies.

© 2018 GSK group of companies or its licensor.

RELENZA ROTADISKS: AUST R 66962

9 January 2018

Version 4.0