

RELENZA

Zanamivir 5 mg/blister

Consumer Medicine Information

WHAT IS IN THIS LEAFLET

Please read this leaflet carefully before you start taking 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 RELENZA IS USED FOR

RELENZA is a medicine used to treat Influenza, or "flu", which is caused by a virus 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 certain 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.

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

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 lactose.
- Do not take RELENZA if you have 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.

Sudden changes in behaviour, having hallucinations or fits

Flu can cause sudden changes in behaviour, such as becoming very confused or unresponsive, having hallucinations (seeing, hearing, or feeling things not there), or having 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.

If you get any of these symptoms contact your doctor immediately.

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, 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.

- 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).

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.

You should start taking RELENZA as soon as possible, preferably within two days, after developing symptoms to get the best effect.

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

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.

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 for advice (0800 POISON or 0800 764 766), 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.

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.

If this occurs stop taking RELENZA and contact your doctor immediately.

There have been rare reports of wheezing and shortness of breath in people with asthma or chronic lung

disease after taking RELENZA. More rarely, some shortness of breath has occurred in people who do not suffer from asthma or respiratory disease.

People with this problem should report any concerns to their 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.

There have also been rare reports of allergic type reactions which include swelling of the face and throat, skin rash and hives.

These symptoms may not necessarily signify a hypersensitivity reaction (see below).

RELENZA is otherwise, generally well tolerated. In clinical studies some side effects were observed. 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
- difficulty in breathing
- hay fever
- lumpy rash ("hives")
- fainting

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

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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: two for the morning and two for the evening. There are five disks in each pack, one for each day.

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), a 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.

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