NEW ZEALAND CONSUMER MEDICINE INFORMATION

RAZENE®

Cetirizine hydrochloride 10mg Tablets

What is in this leaflet

Please read this leaflet carefully before you start taking RAZENE.

This leaflet answers some common questions about RAZENE.

It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor or pharmacist has weighed the risks of you taking RAZENE against the benefits they expect it will 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 RAZENE is taken for

The most common form of allergy is hayfever. This is a seasonal disorder occurring during spring and summer and is caused mainly by airborne pollens. Typical symptoms include sneezing, runny nose and itchy, watery eyes. For some, these symptoms occur throughout the year, often caused by an allergy to house dust mites or animal fur.

In addition to inhaled allergies there are those caused by eating certain foods, or through contact with certain medicines or chemicals. With these, symptoms appear mainly as skin rashes.

All the symptoms described are due to what is called an allergic reaction between the allergens (pollen, dust, etc.) and certain cells in the body. This reaction triggers the release of

a number of chemical substances which irritate the body. One of these chemical substances is histamine. It is best to try and avoid exposure to the allergens that affect you; however, this is not always possible.

There are a number of medicines available for treating allergies, the most common of these are called antihistamines - because they counteract the effects of histamine. Antihistamines may also be used to treat allergic conjunctivitis, insect bites and hives. One such antihistamine that treats allergies is RAZENE.

RAZENE is an anti-allergic used to treat hayfever and other allergic conditions. It is fast-acting, usually within 20 minutes after taking it, non-sedating and its effects last for 24 hours, so you only need to take it once a day.

Ask your pharmacist or doctor if you have any questions about why this medicine has been prescribed for you.

Your pharmacist or doctor may have prescribed it for another reason.

RAZENE is only available from a pharmacy.

Before you take RAZENE

When you must not take it

Do not take RAZENE if you have an allergy to any of the following:

- any medicine containing cetirizine
- hydroxyzine (another antihistamine related to cetirizine)
- any of the ingredients listed at the end of this leaflet.



Do not take RAZENE if you have end stage kidney disease.

Do not give this medicine to a child under the age of 2 years.

Do not take this medicine after the expiry date printed on the pack or if the packaging is torn or shows signs of tampering. If it has expired or is damaged, return it to your pharmacist for disposal.

If you are not sure whether you should start taking this medicine, talk to your pharmacist or doctor.

Before you start to take it

Tell your pharmacist or doctor if:

- you are allergic to any other medicines, foods, preservatives or dyes
- you suffer from fits / seizures / convulsions / epilepsy
- you have kidney problems
- you have any other medical conditions
- you are pregnant, plan to become pregnant, or are breastfeeding. Your pharmacist or doctor can discuss with you the risks and benefits involved.

RAZENE contains lactose.

If you have been told by your doctor that you have intolerance to some sugars, tell your doctor or pharmacist before taking it.

If you have not told your pharmacist or doctor about any of the above, tell him/her before you start taking RAZENE.

Taking other medicines

Tell your doctor or pharmacist if you are taking any other medicines, including any that you get without a prescription from your pharmacy, supermarket or

health food shop.

Some medicines and RAZENE may interfere with each other. One of these is **Ritonavir** - an antiviral medicine used to treat HIV.

This medicine may be affected by RAZENE or may affect how well it works. You may need different amounts of your medicine, or you may need to take different medicines.

Your doctor and pharmacist have more information on medicines to be careful with or avoid while taking RAZENE.

How to take RAZENE

Follow all directions given to you by your doctor or pharmacist carefully.

They may differ from the information contained in this leaflet.

If you do not understand the instructions on the box, ask your doctor or pharmacist for help.

Your doctor may tell you to take different doses. If so, follow their instructions.

How much to take

Your pharmacist or doctor will tell you how much RAZENE you need to take each day. It is important that you take RAZENE as directed by your pharmacist or doctor. Do not take more than the recommended dose.

If you do not understand the instructions on the box, ask your doctor or pharmacist for help.

Adults and children over 12 years of age

The usual dose is one tablet (10mg) daily as a single dose.

Individuals will vary in their response to medicines and this applies to RAZENE also:

 some people may only require half the daily dose, i.e. 5mg for those who may feel drowsy if they

- take the recommended dose of 10mg
- some people with kidney problems may need a reduced dose. Talk to your pharmacist or doctor about a suitable dose.

The maximum recommended daily dose for adults is 20mg. Do not exceed this dose unless told to do so by your pharmacist or doctor.

Children 6-12 years of age

The recommended dose is half a tablet (5mg) or one tablet (10mg) once daily.

Children 2-6 years of age

The recommended dose is half a tablet (5mg) once daily.

How to take it

Swallow the tablets whole with a full glass of water.

When to take it

Take your medicine at about the same time each day.

Taking it at the same time each day will have the best effect. It will also help you remember when to take it.

How long to take it

You can stop taking RAZENE when you obtain relief from your symptoms. It can be restarted if your symptoms recur.

If your condition does not improve after a few days or is not well controlled by RAZENE, speak to your pharmacist or doctor.

If you forget to take it

If it is almost time for your next dose, skip the dose you missed and take your next dose when you are meant to.

Otherwise, take it as soon as you remember, and then go back to taking your medicine as you would normally.

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

This may increase the chance of you getting an unwanted side effect.

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

If you have trouble remembering to take your medicine, ask your pharmacist for some hints.

If you take too much (overdose)

Immediately telephone your doctor or the National Poisons Information Centre (0800 POISON or 0800 764 766) for advice, or go to Accident and Emergency at the nearest hospital, if you think that you or anyone else may have taken too much RAZENE. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

Some of the symptoms/signs of an overdose include dizziness, headache, diarrhoea, fast heartbeat and itchiness of the skin.

While you are using RAZENE

Things you must do

If you are about to be started on any new medicine, remind your doctor and pharmacist that you are taking RAZENE.

Tell any other doctors, dentists, and pharmacists who treat you that you are taking this medicine.

If you are going to have surgery, tell the surgeon or anaesthetist that you are taking this medicine. It may affect other medicines used during surgery.

If you become pregnant while taking this medicine, tell your doctor immediately.

If you are about to have any blood tests, tell your doctor that you are using/taking this medicine.

It may interfere with the results of some tests.

Things you must not do

Do not take RAZENE to treat any other complaints unless your doctor tells you to.

Do not give your medicine to anyone else, even if they have the same condition as you.

Do not take this medicine 3 days before any allergy tests.

This medicine will interfere with the results of an allergy test.

Things to be careful of

Although this medicine is unlikely to affect your ability to drive or operate machinery, a few people may be impaired and care should be taken.

If you feel drowsy after taking RAZENE, be cautious about driving or operating machinery for 8 hours. In such cases it may be best to take RAZENE before you go to bed at night.

Be careful when drinking alcohol while you are taking this medicine.

If you drink alcohol, dizziness, lightheadedness, drowsiness, alertness and motor performance may be worse.

Try to avoid contact with known substances you are allergic to.

Side effects

Tell your pharmacist or doctor as soon as possible if you do not feel well while you are taking RAZENE.

This medicine helps most people with allergies but it may have unwanted side effects in a few people.

All medicines can have some unwanted effects. Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some of the side effects.

Ask your doctor or pharmacist to answer any questions you may have.

Do not be alarmed by the following lists of side effects. You may not experience any of them.

Tell your pharmacist or doctor if you notice any of the following and they worry you:

- drowsiness
- headache
- tiredness
- dizziness
- · dry mouth
- nausea
- diarrhoea
- difficulty urinating
- sore throat
- runny nose
- · abdominal pain
- agitation, aggression, depression or hallucination
- confusion
- insomnia
- weight gain
- blurred vision
- tingling or numbness of the hands or feet
- movement disorder
- tremor
- increased appetite
- nightmares
- vertigo.

Tell your doctor immediately if you notice any of the following:

- swelling of the face, lips or tongue which may cause difficulty in swallowing or breathing
- asthma, wheezing, shortness of breath
- sudden or severe itching, skin rash, hives
- unusual bruising or bleeding
- · fast or irregular heart beat
- fever
- · fits or seizures
- · nausea or vomiting
- yellowing of the skin and eyes
- · dark coloured urine
- · difficulty passing urine
- suicidal thoughts.

These side effects are usually rare but can be serious and need urgent medical attention.

The list of side effects mentioned above is not complete. If you should suffer from any of these side effects or any other undesired effect please tell your pharmacist or doctor.

Ask your doctor or pharmacist to answer any questions you may have.

After using RAZENE

Storage

Keep your tablets in the pack until it is time to take them.

If you take the tablets out of the pack they may not keep well.

Keep your tablets in a cool dry place where the temperature stays below 25°C.

Do not store RAZENE or any other medicine in the bathroom or near a sink. Do not leave it on a window sill or in the car. Heat and dampness can destroy some medicines.

Keep it where children cannot reach it.

A locked cupboard at least one-anda half metres above the ground is a good place to store medicines.

Disposal

If your doctor tells you to stop taking this medicine or the expiry date has passed, ask your pharmacist what to do with any medicine that is left over.

Product description

What it looks like

RAZENE tablets are white, capsule shaped, film coated tablets marked "CZ" breakline "10" on one side and "G" on the reverse.

Ingredients

RAZENE contains 10mg of cetirizine hydrochloride as the active ingredient.

It also contains:

- lactose
- pregelatinised maize starch
- povidone
- magnesium stearate.

The film coat contains:

- hydroxypropylmethyl cellulose
- titanium dioxide
- macrogol.

Contains Sugars as lactose.

If you want to know more

Should you have any questions regarding this product, please contact your pharmacist or doctor.

Who supplies this medicine

Distributed in New Zealand by:

Viatris Ltd PO Box 11-183 Ellerslie AUCKLAND www.viatris.co.nz Telephone 0800 168 169

Date of Preparation

03 February 2023 (Based on datasheet dated 03 February 2023)

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