

# Zilarex®

*cetirizine hydrochloride tablets*

## Consumer Medicine Information

### WHAT IS IN THIS LEAFLET

This leaflet answers some common questions about Zilarex. 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 has weighed the risk of you taking Zilarex against the benefits it is expected to 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 want to read it again.

### WHAT ZILAREX IS USED FOR

The name of your medicine is Zilarex. It contains the active ingredient cetirizine hydrochloride.

Cetirizine hydrochloride is an antihistamine used to relieve the symptoms of hayfever (also known as seasonal allergic rhinitis) and perennial allergic rhinitis e.g. sneezing, an itchy or runny nose and itchy, watering or red eyes. It is also used to treat some itchy skin rashes such as hives (also known as chronic idiopathic urticaria).

**Ask your doctor if you have any questions about why Zilarex was prescribed for you.**

Your doctor may have prescribed Zilarex for another reason.

There is no evidence that Zilarex is addictive.

### BEFORE YOU TAKE ZILAREX

*When you must not take it*

**Do not take this medicine if you have an allergy to:**

- cetirizine hydrochloride, the active ingredient, or to any of the other ingredients listed at the end of this leaflet under Product Description
- any other similar medicines such as hydroxyzine (another antihistamine, related to cetirizine)

Some of the symptoms of an allergic reaction may include:

- shortness of breath
- wheezing or difficulty breathing
- swelling of the face, lips, tongue or other parts of the body
- rash, itching or hives on the skin

**Do not take this medicine if you have or have had severely impaired kidney function.**

**Do not take this medicine if you are pregnant.**

It may affect your developing baby if you take it during pregnancy.

**Do not breastfeed if you are taking this medicine.**

The active ingredient in Zilarex passes into breast milk and there is a possibility that your baby may be affected.

**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 doctor or pharmacist.**

*Before you start to take it*

**Tell your doctor or pharmacist if you have allergies to any other medicines, foods, preservatives or dyes.**

**Tell your doctor or pharmacist if you are pregnant or intend to become pregnant.**

Like most medicines, Zilarex is not recommended for use during pregnancy. If there is a need to consider Zilarex during your pregnancy, your doctor or pharmacist will discuss with you the benefits and risks of using it.

**Tell your doctor or pharmacist if you are breastfeeding or plan to breastfeed.**

Your doctor or pharmacist will discuss the possible risks and benefits of using Zilarex during breastfeeding.

**Tell your doctor or pharmacist if you have or have had any medical conditions, especially the following:**

- epilepsy (fits/seizures/convulsions)
- kidney problems.

**Zilarex 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 doctor or pharmacist about any of the above, tell him/her before you start taking Zilarex.**

### *Taking other medicines*

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

Some medicines may be affected by Zilarex or may affect how well it works. Your doctor or pharmacist can advise you about other medicines you might need to be careful with, while taking Zilarex.

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## HOW TO TAKE ZILAREX

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**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, ask your doctor or pharmacist for help.**

### *How much to take*

The usual dose for adults and children 12 years and over is one tablet daily. Some adults may require only half a tablet per day (e.g. people with kidney problems). Some adults may require the maximum dose of two tablets (20mg) per day.

The usual dose for children 6-12 years of age is half a tablet twice a day. Zilarex is not recommended for children under 6 years of age.

**Ask your doctor or pharmacist if you are unsure of the correct dose for you.**

They will tell you exactly how much to take.

**Follow the instructions they give you.**

If you take the wrong dose, Zilarex may not work as well and your problem may not improve.

### *How to take it*

The tablets should be swallowed with a glass of water. They can be taken with or without food.

If you need to break the Zilarex tablet, hold tablet with both hands and snap along break line.

### *When to take Zilarex*

**If this medicine makes you feel drowsy, take the tablet in the evening or at bed time.**

**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.

Zilarex can be taken when allergic symptoms start showing:

- hayfever may begin with itchiness in the throat, nose or eyes
- hives will usually cause your skin to itch and you may notice pink lumps appearing.

People suffering from hayfever will usually need to take Zilarex during spring and summer, when there is more pollen in the air to trigger symptoms.

### *How long to take Zilarex*

You can stop taking Zilarex 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 it is not well controlled by Zilarex, speak to your doctor or pharmacist.

### *If you forget to take it*

If you (or a child 12 years or over) forget to take a dose, take one dose as soon as you remember, but wait at least 12 hours before taking the next dose. If you forget to give your child (6-12 years) their dose, give them one dose as soon as you remember, but wait at least 6 hours before giving the next dose to your child.

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

This may increase the chance of 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*

**Immediately telephone your doctor or the Poisons Information Centre (telephone Australia 13 11 26 or New Zealand 0800 POISON or 0800 764 766) or go to Accident and Emergency at your nearest hospital, if you think that you or anyone else has taken too much Zilarex. Do this even if there are no signs of discomfort or poisoning.** You may need urgent medical attention.

If you take too much Zilarex, you may feel confused, drowsy, dizzy, restless, tired and may experience diarrhoea, headaches, rash, a rapid heart rate and tremors.

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## WHILE YOU ARE TAKING ZILAREX

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### *Things you must do*

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

**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.**

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

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

If you already know which substances set off your allergies, keep a supply of Zilarex tablets ready so you know you can control the symptoms when they start appearing.

### *Things you must not do*

**Do not take Zilarex 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.**

### *Things to be careful of*

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

Zilarex may cause dizziness, light-headedness, tiredness or drowsiness in some people. Make sure you know how you react to Zilarex before you drive a car, operate machinery, or do anything else that could be dangerous if you are dizzy or light-headed. If this occurs do not drive. If affected, children should be careful when riding bicycles or climbing trees.

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

If you drink alcohol, dizziness, light-headedness, drowsiness, alertness and motor performance may be worse.

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

Hives are sometimes caused by allergy to certain foods; you should talk to your doctor for more information or if you are worried about this.

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## SIDE EFFECTS

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

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

**Do not be alarmed by this list of possible side effects. You may not experience any of them.**

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

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

- drowsiness, sleepiness, fatigue
- dizziness or lightheadedness
- dry mouth
- headache
- stomach upset e.g. changes in bowel habits, diarrhoea, nausea and vomiting
- a restless or agitated feeling
- rash
- difficulty breathing/shortness of breath and wheezing
- rapid heart rate
- loss of or increase appetite
- unintentional weight change
- generally feeling ill.

These side effects are usually mild and short-lived.

**Tell your doctor or pharmacist if you notice anything that is making you feel unwell.**

Other side effects not listed above may occur in some patients.

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## AFTER TAKING ZILAREX

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### *Storage*

**Keep Zilarex in the original packaging until you need to take it.**

If you take it out of its original container it may not keep well.

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

**Do not store Zilarex 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-and-a-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.

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## PRODUCT DESCRIPTION

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### *What it looks like*

Zilarex 10 mg: white, oblong-shaped tablets with a score notch on one side. Available in blister packs of 10 or 30 tablets.

### *Ingredients*

Active ingredient:

- Zilarex 10 mg - 10mg cetirizine hydrochloride.

Inactive ingredients:

- lactose
- cellulose microcrystalline
- silica colloidal anhydrous

- magnesium stearate
- hypromellose
- titanium dioxide
- macrogol 4000.

This medicine does not contain sucrose, gluten, tartrazine or any other azo dyes.

### *Supplier*

#### **Sandoz Pty Ltd**

ABN 60 075 449 553

19 Harris St

Pymont NSW 2009

Tel: 1800 634 500

#### **Novartis New Zealand Ltd**

Private Bag 65904 Mairangi Bay

Auckland 0754

New Zealand

Tel: 0800 354 335

This leaflet was revised in August 2011.

### *Australian registration number:*

Zilarex 10 mg tablets:

AUST R 120710 (blisters)