



## **Patient package insert according to Pharmacists' Regulations (Preparations) – 1986**

This medicine can be sold without a physician's prescription

### **ZYLLERGY® CAPLETS 10 mg**

Each caplet contains Cetirizine dihydrochloride 10 mg

Inactive ingredients and allergens in the medicine: see section 6 "Additional information" and in section 2 "Important information about some of the ingredients of the medicine".

**Read this entire leaflet carefully before using the medicine.** This leaflet contains concise information about the medicine. If you have any further questions, ask the doctor or pharmacist.

Take this medicine according to the instructions in section 3 "How to use the medicine?" in this leaflet. Consult a pharmacist if you need further information. Refer to a doctor if the symptoms of your illness get worse or if they do not improve after 3 days.

### **1. What is the medicine intended for?**

Antihistaminic drug for the treatment of allergies. For the treatment of symptoms of seasonal allergic rhinitis (hay fever) and perennial allergic rhinitis (such as dust or pet allergies) and for the treatment of chronic idiopathic urticaria (hives), which is characterized by skin irritation (e.g.: itching, rash).

For adults and for children over the age of 6 years.

**Therapeutic group:** antihistamines

Cetirizine dihydrochloride, the active ingredient in the medicine, is an antihistamine. It blocks the effects of a substance called histamine, which occurs naturally in the body. Histamine is involved in allergic reactions.

Antihistamines, like cetirizine, relieve the unpleasant symptoms and discomfort associated with these conditions, such as sneezing, irritated, runny, and stuffy nose, itchy, red and watering eyes, and skin rashes.

### **2. Before using the medicine**

**Do not use the medicine if:**

- You are hypersensitive (allergic) to cetirizine dihydrochloride or to any of the other ingredients this medicine contains (see section 6), to hydroxyzine or to any piperazine derivatives (similar piperazine-group active ingredients of other medicines).
- You have a severe kidney disease (severe renal failure with creatinine clearance below 10 ml/min).

### **Special warnings regarding the use of the medicine**

**Before taking Zyllergy tell the doctor if:**

- You have kidney failure. If necessary, you will take a lower dose of this medicine. The new dose will be determined by your doctor.
- You have problems passing urine (like spinal cord problems, or prostate or bladder problems).
- You suffer from epilepsy or are at risk of having seizures.
- You are scheduled for allergy testing. Ask your doctor if you should stop taking **Zyllergy** for several days before the test. This medicine may affect your allergy test results.

### **Children and adolescents**

Do not give this medicine to children under 6 years old.

## **Drug interactions**

**If you are taking or have recently taken other medicines, including non-prescription medicines and nutritional supplements, tell the doctor or pharmacist.**

## **Use of the medicine and food**

The medicine can be taken with or without food. Food does not affect absorption of this medicine.

## **Use of the medicine and alcohol consumption**

No clinically significant interactions were observed between alcohol (at the blood level of 0.5 per mille [gram/liter], equivalent to one glass of wine) and cetirizine, when used at the recommended doses. However, there is no safety information about taking higher doses of cetirizine with alcohol. Hence, as with all antihistamines, it is advisable to avoid taking **Zyllergy** at the same time as consuming alcohol.

## **Pregnancy and breastfeeding**

If you are pregnant or breastfeeding, think you may be pregnant or are planning to become pregnant, consult a doctor before using this medicine.

Do not take **Zyllergy** during pregnancy. Accidental use of the medicine by a pregnant woman should not produce any harmful effects on the fetus.

Nevertheless, the medicine should only be administered if necessary and after consulting a doctor.

Cetirizine passes into breast milk. So, do not take **Zyllergy** when you are breastfeeding unless it's your doctor's advices.

## **Driving and using machines**

Clinical studies have produced no evidence of impaired attention, alertness and driving capabilities after taking **Zyllergy** at the recommended dose.

You should closely observe your response to the medicine after you have taken **Zyllergy** if you are intending to drive, engage in potentially hazardous activities or operate machinery. Do not exceed the recommended dose.

As for children, they should be warned about riding a bicycle or playing near roads etc.

## **Important information about some of the ingredients of the medicine**

**Zyllergy** contains lactose. If you have been told by your doctor that you have intolerance to certain sugars, consult the doctor before taking this medicine.

## **3. How to use the medicine?**

Always use this medicine exactly as described in this leaflet or as your doctor or pharmacist have told you. Check with a doctor or pharmacist if you are not sure about the dosage and the manner of treatment with the medicine.

The usual recommended dosage, unless otherwise instructed by a doctor:

Children 6-12 years of age: half a caplet twice a day in the morning and in the evening or one caplet once a day.

Children weighing less than 30 kg: half a caplet once daily.

Adults and children over 12 years of age: maximum one caplet per day.

Adults over the age of 65 and patients with impaired hepatic or renal function: Consult a doctor.

If you feel drowsy or dizzy, taking half a caplet twice a day can reduce these effects.

**Do not exceed the recommended dose.**

The duration of treatment depends on the type, duration and course of your complaints. Ask your doctor for advice.

Swallow the medicine with a glass of water.

The caplets can be halved. There is no information regarding crushing and chewing.

### **If you have accidentally taken a higher dosage**

If you think you have taken an overdose of **Zylergy**, consult your doctor. Your doctor will decide what measures, if any, should be taken. After an overdose, the side effects described below may occur with increased intensity. There have been reports of undesirable effects, such as confusion, diarrhea, dizziness, tiredness, headache, feeling unwell, dilated pupils, itching, restlessness, sedation, sleepiness, stupor, abnormal rapid heart rate, tremors and urinary retention.

### **If you forgot to take the medicine**

Do not take a double dose to make up for a forgotten dose. If you forgot to take the caplet at the usual time, take it as soon as you remember, but wait at least 24 hours before taking the next dose.

### **If you stop taking the medicine**

Rarely, intense itching (pruritus) and/or hives (urticaria) may return if you stop taking **Zylergy**.

**Do not take medicines in the dark! Check the label and the dose each time you take a medicine. Wear glasses if you need them.**

**If you have further questions on the use of this medicine, consult the doctor or pharmacist.**

## **4. Side effects**

Like any medicine, the use of **Zylergy** can cause side effects in some users. Do not be alarmed when reading the list of side effects. You may not suffer from any of them.

**The following side effects are rare or very rare, but you must stop taking the medicine and talk to your doctor immediately if you notice them:**

- Allergic reactions, including severe reactions and angioedema (serious allergic reaction, which causes swelling of the face or throat). These reactions may start soon after you first take the medicine, or they might start later.

**Common side effects** (effects that occur in 1-10 out of 100 users):

- Somnolence (sleepiness)
- Dizziness, headache
- Inflammation of the pharynx and throat (pharyngitis), inflammation of the nose mucosa (rhinitis) (in children)
- Diarrhea, nausea, dry mouth
- Fatigue

**Uncommon side effects** (effects that occur in 1-10 out of 1,000 users):

- Agitation
- Paresthesia (abnormal feeling of the skin)
- Abdominal pain
- Pruritus (itchy skin), rash
- Asthenia (extreme fatigue), malaise (feeling unwell)

**Rare side effects** (effects that occur in 1-10 out of 10,000 users):

- Allergic reactions, some severe (very rare)

- Depression, hallucination, aggression, confusion, insomnia
- Seizures
- Tachycardia (heart beating too fast)
- Abnormal liver function
- Urticaria (hives)
- Edema (swelling)
- Weight gain

**Very rare side effects** (effects that occur in less than 1 in 10,000 users):

- Thrombocytopenia (low levels of blood platelets)
- Tics (involuntary, non-functional motoric movements)
- Syncope (fainting), dyskinesia (involuntary movements), dystonia (abnormal prolonged muscular contraction), tremor, dysgeusia (altered taste)
- Blurred vision, difficulty focusing (accommodation disorder), eyes making uncontrolled circular movements
- Rash in a specific site resulting from using this medicine
- Passing urine abnormally (bed wetting, pain and/or difficulty passing urine)

**Side effects with unknown frequency** (effects for which a frequency has not yet been determined):

- Joint pain
- Rash with blisters containing pus
- Increased appetite
- Suicidal ideation (recurring thoughts of or preoccupation with suicide), nightmares
- Memory loss, memory problems
- Vertigo (sensation of spinning or movement)
- Urinary retention (inability to completely empty the bladder)
- Pruritus (intense itching) and/or urticaria (hives) when stopping the medicine
- Hepatitis (inflammation of the liver)

**If a side effect occurs, if one of the side effects worsens or if you suffer from a side effect which is not mentioned in this leaflet, consult the doctor.**

Side effects can be reported to the Ministry of Health by clicking the link “דיווח על תופעות לוואי” “עקב טיפול תרופתי” found on the homepage of the Ministry of Health website ([www.health.gov.il](http://www.health.gov.il)) directing to the online form for reporting side effects or via the link: <https://sideeffects.health.gov.il>

## **5. How to store the medicine?**

- Avoid poisoning! This medicine and any other medicine must be stored in a closed place out of the reach and sight of children and/or infants to avoid poisoning. Do not induce vomiting unless explicitly instructed to do so by the doctor.
- Do not use the medicine after the expiry date (תאריך תפוגה) stated on the package. The expiry date refers to the last day of that month.
- **Storage conditions:** Store below 25°C.
- Do not throw away any medicines via wastewater or household waste. Ask the pharmacist how to throw away medicines you no longer use. These measures will help protect the environment

## **6. Additional information:**

**In addition to the active ingredient, the medicine also contains:**

Lactose monohydrate, maize starch, starch pregelatinised, povidone, talc, basic butylated methacrylate copolymer, magnesium stearate, titanium dioxide, macrogol 6000.

**What the medicine looks like and what the package contains:**

White caplet with a score line on one side.

Approved package sizes: 7, 10, 14, 20, 21 caplets.

Not all package sizes may be marketed.

Revised in October 2023 according to MOH guidelines

**Drug registration number at the national drug registry of the Ministry of Health:**

116-43-29833-00

**Manufacturer and registration holder:**

Dexcel Ltd.,

1 Dexcel St., Or Akiva 3060000, Israel