

This medicine can be sold without a physician's prescription.

## ZYLLERGY® - Caplets 10 mg

### Each caplet contains:

Cetirizine dihydrochloride 10 mg

The excipients are listed in section 6.

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

**This medicine is not intended for children under 6 years of age.**

Use it in the correct manner. Consult a pharmacist if you need additional information. Refer to the physician, if the symptoms of the illness get worse or do not improve within a few days.

### 1. What is the medicine used for?

Zyllergy is intended for the treatment of symptoms of seasonal allergic rhinitis (hay fever) or perennial (with symptoms of: sneezing, runny nose, itching of the nose or eyes, tears) and for the treatment of chronic idiopathic urticaria (hives) which is characterized by skin irritation (e.g. itching, rash).

### Therapeutic group:

Zyllergy belongs to a class of medicines called antihistamines.

### 2. Before you take the medicine:

#### Do not use the medicine if:

- you are hypersensitive (allergic) to the active ingredient, to any of the other ingredients of this medicine (see section 6), another hydroxyzine containing medicine of the antihistamines family or to drugs from the piperazine family, for example: buclizine, cycizine, meclozine, levocetirizine.
- you are breastfeeding.
- you suffer from severe kidney disease or severe renal failure (creatinine clearance below 10 ml/min).
- you have problems of urinary retention.
- you have an intolerance to some sugars (this medicine contains lactose).

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

**Before taking the medicine tell the physician and consult him if:**

- you are pregnant, think you might be pregnant or trying to get pregnant (see section 'Pregnancy and breastfeeding').
- you are sensitive to any type of food or medicine.
- you suffer or have suffered from impaired function of the kidney/urinary system, the prostate, the liver, the heart and/or blood vessels, from emphysema or chronic bronchitis.

- you suffer from epilepsy or you are at risk of seizures.
- you have predisposition factors of urinary retention (eg: spinalcord lesion, prostatic hyperplasia) as cetirizine increases the risk of urinary retention.
- Prior to allergy tests, stop taking the medicine for 3 days before the test, because taking this medicine can affect the test results.
- Do not use this medicine frequently or for a prolonged period of time without consulting a physician.
- Take particular care to adequate oral hygiene, as a long-term treatment with this medicine can lead to a higher risk of infections of the teeth or gums.

**Please tell a physician or pharmacist if you are taking or have recently taken any other medicines, including non-prescription drugs and nutrition supplements.**

**Especially inform the physician or pharmacist if you are taking medicines that affect the nervous system such as sleeping pills, medication for depression, sedatives, Ritonavir (to treat HIV infection) or theophylline.**

- **Do not take Zyllergy together with other drugs from the piperazine family, for example: buclizine, cycizine, meclozine, levocetirizine.**

### Use of this medicine and food

The medicine can be taken with food.

### Use of this medicine and alcohol consumption

**Do not drink wine or alcoholic beverages during the treatment with the medicine.**

### Pregnancy and breastfeeding

Do not use the medicine without consulting a physician before starting treatment if you are pregnant, think you might be pregnant or trying to become pregnant.

As with other drugs, use of Zyllergy should be avoided by pregnant women. Accidental use of the drug by a pregnant woman should not produce any harmful effects on the fetus. Nevertheless, the administration of the medicine should be discontinued.

Do not use the medicine when you are breastfeeding.

### Driving and use of machinery

This medicine can cause drowsiness and/or fatigue for some people. If you feel this effect after using Zyllergy, avoid any activity that requires alertness such as: driving a vehicle or operating dangerous machinery. In regard to children, they

should be warned against riding a bicycle or playing near roads etc.

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

Zyllergy contains lactose. If you have been previously told by a physician that you have intolerance to certain sugars, consult the physician before starting treatment with this medicine.

### 3. How to use this medicine

Check with a physician or pharmacist if you are not sure.

**This medicine is not intended for children under 6 years of age.**

Usual recommended dosage unless otherwise instructed by a physician:

Children 6-12 years of age: half a caplet twice a day (half a caplet in the morning and half a caplet in the evening) or 1 caplet once a day.  
Children weighing less than 30 kg: half a caplet once daily.

Adults and children over 12 years of age: 1 caplet a day at most.

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

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

Swallow the medicine with water, can be swallowed with food. Can be crushed/halved.

There is no information regarding chewing.

**Do not exceed the recommended dose.** If you feel that the effect of Zyllergy is too weak or too strong, please consult your physician. If symptoms worsen or do not improve within a few days, consult a physician.

**If you have taken an overdose or if a child has accidentally swallowed the medicine, proceed immediately to a physician or a hospital emergency room and bring the package of the medicine with you.**

If you have accidentally taken a higher dosage side effects may occur such as sleepiness, agitation, irritability, drowsiness, confusion, diarrhoea, dizziness, tiredness, headache, ailing, dilator (widening) of the pupil, itching, sedation, stupor, abnormal rapid heart rate, tremors and urinary retention, so remember not to drive in this situations.

If you forget to take this medicine at the specified time, do not take a double dose. Take the next dose at the regular time and consult a physician.

Do not take medicines in the dark! Check the label

and the dose each time you take your medicine. Wear glasses if you need them.

If you have any further questions regarding the use of this medicine, consult a physician or pharmacist.

### 4. Side effects

Like all medicines, the use of Zyllergy can cause side effects, although not everybody gets them. Do not be alarmed while reading the list of side effects, you may not suffer from any of them.

**Stop treatment and refer to a physician immediately if the following effects develop:**

- signs of shock or severe allergic reaction (very rare) appear such as: shortness of breath/difficulty breathing, rash, itching, fever; swelling of the throat, face, eyelids, neck, tongue, lips and/or other parts of the body. This reaction may either appear immediately after taking the medicine for the first time or later on.
- tendency to bruise and/or bleed more than usual.
- convulsions/fits.
- restlessness, skin sensitivity to touch, drowsiness, stomach discomfort.
- headaches, diarrhea in children, dryness of the mouth, dizziness, tiredness. These side effects occur often.
- weakness or malaise, diarrhea. These side effects occur infrequently.
- thoughts about committing suicide (very rare).
- hallucinations, confusion, changes in liver function such as abnormal liver function tests, rapid heart rate (occurs rarely), fainting.

### Additional side effects:

**Common side effects – effects that appear in 1-10 users out of 100:**

sleepiness, nausea, stomach pain, dizziness, pharyngitis (sore throat), nasal cold-like symptoms (in children only), swelling or irritation in the nose (rhinitis), nosebleed.

**Uncommon side effects – effects that appear in 1-10 users out of 1,000:** itching and/or rash, paraesthesia (abnormal feeling of the skin), tingling of hands and feet, restlessness, blisters on the skin, nervousness, insomnia.

**Rare side effects – effects that appear in 1-10 users out of 10,000:** edema (general swelling due to fluid retention), hepatitis, weight gain, aggression, depression, seeing or hearing things that do not exist (hallucinations), urticaria (swelling, redness and itchiness of the skin), cholelithiasis, glomerulonephritis, hemolytic anemia, involuntary facial movements, severe hypotension,

low platelets count (thrombocytopenia), movement disorders, muscle stiffness, tremors, tics (sudden involuntary repetitive muscles movements), vision disorder such as blurred vision, urinary incontinence, difficulty/pain when passing urine, changes in sense of taste, weight gain.

**Very rare side effects – effects that appear in less than one user out of 10,000:** difficulty in focusing vision, involuntary rolling of the eyes, abnormal bleeding or bruising, bad taste in the mouth, involuntary or unusual movements of the limbs, neck and shoulders muscle spasms, skin swelling especially of the face, fainting, recurring rash, bedwetting, fixed drug eruption, abnormal excretion of urine.

**Additional side effects:** loss of memory and/or memory disorder, difficulty concentrating, anorexia, flushing, salivation, urinary retention, heart failure, hypertension, abnormal coordination, difficulty controlling movement, impairment in producing sound, hyperactivity (abnormally increased muscular activity or function), high muscle tension, low pain sensitivity, leg cramps, migraine, inflammation of the spinal cord nerves, paralysis, drooping eyelids, spasms, vertigo, visual field impairments, worsening of caries, constipation, indigestion, belching, flatulence, gastritis, hemorrhoids, increased appetite, black stools, rectal bleeding, inflammation of the mouth (stomatitis) including ulcerative inflammation, changes in tongue color, tongue edema, cystitis, blood in urine, urgent urination, excessive urination, urinary incontinence, urinary tract infections, deafness, earache, ototoxicity, tinnitus, dehydration, diabetes, thirst, joint pain, arthritis, osteoarthritis, muscle weakness, muscle pain, abnormal thoughts, decreased libido, depersonalization, emotional instability, elation, bad dreams, sleep disturbances, bronchitis, shortness of breath, hyperventilation, increased sputum, pneumonia, respiratory disorder, sinusitis, upper respiratory tract infection, menstrual pain, chest pain (in women), bleeding between cycles, white vaginal discharge, excessive bleeding during menstruation, vaginitis, enlargement of lymph nodes, acne, alopecia, skin infection, dry skin, eczema, furuncles manifestation, hyperkeratosis, hirsutism, increased sweating, photosensitivity reaction, photosensitivity toxic reaction, purpura, seborrhea, skin disorders, skin nodule, impaired sense of smell, loss of taste, blindness, conjunctivitis, eye pain, glaucoma, loss of ability to focus vision, ocular hemorrhage, dry eye, accidental injury, fatigue, back pain, chest pain, abdominal enlargement, heat flashes, leg edema, nasal polyps, pain, swelling around the eyes, stiffness.

**Side effects and drug interactions in children:** Pharyngitis, cough, nasal bleeding, bronchial contraction, vomiting.

Parents should inform the physician of any side

effects and any other medications given to the child!

See the list of special side effects and drug interactions detailed above.

If a side effect appears, if any of the side effects worsen, if you experience side effects not mentioned in this leaflet or if there is a change in your general feeling, consult a physician.

Side effects can be reported to the Ministry of Health by clicking on the link "דיווח על תופעות לוואי עקב טיפול תרופתי" that can be found on the home page of the Ministry of Health website ([www.health.gov.il](http://www.health.gov.il)) directing to the online form of adverse events reporting or via the following link: <https://forms.gov.il/globaldata/getsequence/getsequence.aspx?formType=AdversEffectMedic@moh.gov.il>

### 5. How to store the medicine

- **Avoid poisoning!** This medicine, and all other medicines, must be stored in a safe place out of the reach of children and/or infants, to avoid poisoning. **Do not induce vomiting** unless explicitly instructed to do so by a physician!
- Do not use the medicine after the expiry date (exp. date) stated on the package. The expiry date refers to the last day of that month.
- Store at temperature below 25°C.
- Store in the original package. Do not store different medicines in the same package.

### 6. Additional information:

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

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

Each caplet contains approx. 62 mg lactose.

**What the medicine looks like and contents of the pack:**

White caplets with a score line on one side. Approved package sizes: 5, 7, 10, 14, 20, 21, 28, 30, 56 or 100.

Not all package sizes may be marketed.

This leaflet was checked and approved by the Ministry of Health in January 2016.

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

116 43 29833 00

Zyllergy GSL PIL PB0316-05

Manufacturer and registration holder:

**Dexcel® Ltd**

1 Dexcel St., Or-Akiva 3060000, Israel