

**PATIENT PACKAGE INSERT IN ACCORDANCE WITH THE PHARMACISTS' REGULATIONS (PREPARATIONS) - 1986**

The medicine is dispensed without a doctor's prescription

## N-ALERGYA

### Tablets

**Each tablet contains** Cetrizine dihydrochloride at a dosage of 10 mg. Inactive ingredients are listed in section 6.

**Read this leaflet carefully in its entirety before using the medicine.** This leaflet contains concise information about the medicine. If you have further questions, refer to the doctor or pharmacist.

**The medicine is not intended for children under 6 years of age.** Take the medicine properly. Consult a pharmacist if you need further information.

Refer to the doctor if signs of the disease (symptoms) worsen or do not improve after a few days.

#### 1. WHAT IS THE MEDICINE INTENDED FOR?

For the treatment of seasonal and perennial allergic rhinitis and of chronic urticaria characterized by skin irritation (e.g., itching, rash). For adults and children over the age of 6.

**Therapeutic group:** Antihistamines.

#### 2. BEFORE USING THE MEDICINE

**Do not use the medicine if you are:**

- sensitive (allergic) to the active ingredient, to any of the other ingredients contained in the medicine (see section 6), to another medicine from the antihistamine group that contains hydroxyzine or to other medicines from the piperazine group, e.g., buclizine, cyclizine, meclozine, levocetirizine.
- breastfeeding.
- suffering from severe kidney disease or from severe kidney failure (creatinine clearance lower than 10 ml/min).
- suffering from urinary retention problems.
- intolerant to certain sugars (the preparation contains lactose).

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

**Before treatment with the medicine, tell the doctor and consult with him if:**

- you are pregnant, think you are pregnant or are trying to become pregnant (see Pregnancy and breastfeeding section).
- you are sensitive to any food or medicine.
- you are suffering, or have suffered in the past, from impaired function of the kidney/urinary system, prostate gland, liver, heart and/or blood vessels, from emphysema or chronic bronchitis.
- you are suffering from epilepsy or are at risk for seizures.
- you are suffering from predisposing factors of urinary retention (e.g., spinal cord damage, prostatic hyperplasia) as cetirizine increases the risk of urinary retention.

- Before a diagnostic allergy test, stop taking the medicine 3 days before the test, since taking the medicine can affect the test results.
- Do not use this medicine often or for a prolonged period without consulting the doctor.
- Prolonged treatment with this medicine increases the risk of dental or gingival infections; maintain proper dental hygiene.

**If you are taking, or have recently taken, other medicines, including non-prescription medicines and nutritional supplements, tell the doctor or pharmacist. In particular, inform the doctor or pharmacist if you are taking medicines that affect the central nervous system, such as hypnotics,**

antidepressants, sedatives, ritonavir (to treat HIV, human immunodeficiency virus) or theophylline.

- **Do not use N-Alergya concomitantly with other medicines from the piperazine group, e.g., buclizine, cyclizine, meclozine, levocetirizine.**

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

The medicine can be taken with food.

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

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

#### **Pregnancy and breastfeeding**

If you are pregnant, think you are pregnant or are planning to become pregnant, do not use the medicine without consulting a doctor before starting treatment.

As with other medicines, use of N-Alergya should be avoided during pregnancy. Accidental use of the medicine during pregnancy, will probably not cause harm to the unborn baby. Nonetheless, discontinue use of the medicine.

Do not use the medicine when you are breastfeeding.

#### **Driving and use of machinery**

This medicine can cause drowsiness, fatigue in certain people. If you experience this effect after using N-Alergya, abstain from all activities that require alertness, such as: driving a car or operating dangerous machinery. Children should be cautioned against riding bicycles or playing near the road and the like.

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

N-Alergya contains lactose. If you have been told in the past by a doctor that you have an intolerance to certain sugars, consult the doctor before starting treatment with this medicine.

#### 3. HOW SHOULD YOU USE THE MEDICINE?

Check with the doctor or pharmacist if you are uncertain.

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

The usual dosage, unless instructed otherwise by the doctor:

Children aged 6-12: half a tablet, twice a day, in the morning and evening, or one tablet once a day.

Children weighing less than 30 kg: half a tablet, once a day.

Adults and children from 12 years of age: one tablet per day, at most.

Adults over 65 years of age and patients with impaired liver or kidney function: consult the doctor.

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

Swallow the medicine with a glass of water; it may be taken with food. May be crushed/halved.

There is no information regarding chewing.

**Do not exceed the recommended dose.** Consult the doctor if you feel that the effect of N-Alergya is too weak or too strong. If the symptoms worsen, or if they are not improving after a few days, consult the doctor.

**If you accidentally took an overdose or if a child accidentally swallowed the medicine, immediately refer to a doctor or to a hospital emergency room and bring the package of the medicine with you.**

If you took a higher dosage than recommended, effects may occur, such as: sleepiness, restlessness, drowsiness, irritability, fatigue, confusion, diarrhea, dizziness, headache, malaise, dilated pupils, itching, sedation, stupor, abnormally rapid heart rate, tremor and urinary retention. Remember not to drive in these conditions.

If you forgot to take the medicine at the required time, do not take a double dose. Take the next dose at the usual time and consult a doctor.

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

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

#### 4. SIDE EFFECTS

As with any medicine, use of N-Alergya may 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.

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

- Symptoms of shock or a severe allergic reaction (very rare) occur, 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 can occur immediately after taking the medicine for the first time or can occur later on.
- A tendency to bruise and/or bleed more than usual.
- Seizures/convulsions.
- Restlessness, sensitivity of the skin to touch, drowsiness, stomach discomfort.
- Headaches, diarrhea in children, dry mouth, dizziness, fatigue. These effects are common.
- Weakness or a general unwell feeling, diarrhea – these effects are uncommon.
- Suicidal thoughts (very rare).
- Hallucinations, confusion, changes in liver function, such as abnormal liver function results, accelerated heart rate (occur rarely), fainting.

#### **Additional side effects:**

**Common side effects – effects that occur in 1-10 in 100 users:** sleepiness, nausea, abdominal pain, dizziness, pharyngitis (sore throat), cold-like symptoms in the nose (in children only), nasal swelling or irritation (nasal inflammation), nose bleed.

**Uncommon side effects – effects that occur in 1-10 in 1,000 users:** itching and/or rash, pins and needles, tingling of the hands and legs, restlessness, blisters on the skin, nervousness, insomnia.

**Rare side effects – effects that occur in 1-10 in 10,000 users:** edema (generalized swelling due to fluid retention), hepatitis, weight gain, aggressiveness, depression, seeing or hearing things that do not exist (hallucinations), urticaria (swelling, redness and itching of the skin), cholelithiasis, glomerulonephritis, hemolytic anemia, involuntary facial movements, severe hypotension, low platelet count (thrombocytopenia), movement disturbances, muscular rigidity, tremor, tics (sudden, involuntary, repetitive muscle movements), eyesight problems such as blurred vision, urinary incontinence, pain and/or difficulty passing urine, changes in sense of taste, weight gain.

**Very rare side effects – effects that occur in less than one in 10,000 users:** difficulty focusing vision, involuntary rolling of the eyes, unusual bleeding or bruising, bad taste in the mouth, involuntary or unusual movements of the limbs, spasms of the neck and shoulder muscles, swelling of the skin particularly in the face, fainting, recurring rash, bad wetting, a reddish, oval shaped circular rash, abnormal secretion of urine.

**Additional side effects:** memory loss and/or memory disturbance, difficulty concentrating, anorexia, flushing, drooling, urinary retention, heart failure, hypertension, impaired coordination, difficulty controlling movement, impaired release of voice, hypermotility, high muscle tone, low sensitivity to pain, leg cramps, migraine, inflammation of the nerves of the spinal cord, paralysis, eyelid drooping, convulsions, vertigo, impaired field of vision, worsening of dental caries, constipation, indigestion, belching, flatulence, gastritis, hemorrhoids, increased appetite, black stools, rectal bleeding, inflammation of the mouth (stomatitis), including ulcerative inflammation, discoloration of the tongue, edema of the tongue, inflammation of the bladder, blood in the urine, urinary urgency, frequent urination, urinary incontinence, urinary tract infections, deafness, ear pain, ear toxicity, tinnitus, dehydration, diabetes, thirst, joint pain, joint inflammation, osteoarthritis, muscle weakness, muscle pain, unusual thoughts, decreased libido, depersonalization, emotional instability, elation, bad dreams, sleep disturbances, bronchitis, shortness of breath, hyperventilation, increased phlegm, pneumonia, respiratory disturbances, sinusitis, upper respiratory tract infection, menstrual pains, chest pain (in women), intermenstrual bleeding, white vaginal discharge,

excessive menstrual bleeding, vaginitis, enlargement of the lymph nodes, acne, balding, dermatitis, dry skin, eczema, appearance of pustular abscesses, hyperkeratosis, excessive hairiness, increased sweating, photosensitivity, toxic response to photosensitivity, purpura, seborrhea, skin disturbances, skin nodules, impaired sense of smell, loss of taste, blindness, conjunctivitis, eye pain, glaucoma, loss of ability to focus vision, eye hemorrhage, eye dryness, accidental injury, exhaustion, back pain, chest pain, enlargement of the abdomen, hot flashes, edema in the leg, nasal polyps, pain, edema around the eyes, rigidity.

#### **Side effects and drug interactions in children:**

Pharyngitis, cough, nose bleed, bronchospasm, vomiting.

Parents must inform the attending doctor about any side effect, as well as any additional medicine being given to the child!

See above for special side effects and drug interactions listed.

If a side effect occurs, if one of the side effect worsens, or if you suffer from a side effect not mentioned in the leaflet or if there is a change in your general wellbeing, consult with the doctor.

Side effects can be reported to the Ministry of Health via the online side effects reporting form that can be found on the Ministry of Health homepage [www.health.gov.il](http://www.health.gov.il) or through the following link:

<https://forms.gov.il/globaldata/getsequence/getsequence.aspx?formType=AdversEffectMedic@moh.gov.il>

#### 5. HOW SHOULD THE MEDICINE BE STORED?

- **Avoid poisoning!** This medicine and any other medicine should be kept in a safe place out of the reach of children and/or infants to avoid poisoning. Do not induce vomiting without explicit instruction from the doctor!
- Do not use the medicine after the expiry date (exp. date) that appears on the package. The expiry date refers to the last day of that month.
- Store in a dry place, below 25°C.
- Store in the original package. Do not store different medicines in the same package.

#### 6. FURTHER INFORMATION

- **In addition to the active ingredient, the medicine also contains:** Microcrystalline cellulose, lactose anhydrous, magnesium stearate, colloidal silicon dioxide, HPMC, titanium dioxide, Polyethylene glycol 400. Each tablet contains 35 mg lactose.
- **What the medicine looks like and the contents of the package:** Each package contains 20 white tablets, with a score line on one side.
- **Manufacturer and license holder:** Trima Israel Pharmaceutical Products Maabarot Ltd., Maabarot 4023000 Israel.
- This leaflet was checked and approved by the Ministry of Health in January 2016.
- Registration number of the medicine in the National Drug Registry of the Ministry of Health: 155.16.34652.00

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