Patient leaflet in accordance with the Pharmacists' Regulations (Preparations) - 1986

This medicine is dispensed without a doctor's prescription

N-Alergya

Tablets

Active ingredient

Each tablet contains: cetirizine dihydrochloride 10 mg

Inactive ingredients and allergens: See section 2 under 'Important information about some of this medicine's ingredients' and section 6 'Additional information'.

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

Take this medicine according to the instructions in the section about dosage in this leaflet. Consult your pharmacist if you need further information. Talk to a doctor if your signs of illness (symptoms) get worse or do not improve after 3 days.

1.What is this medicine intended for?

This medicine is used to treat seasonal and perennial allergic rhinitis (hay fever) and chronic idiopathic urticaria (hives) characterized by skin irritation (such as itching, rash). For adults and for children over the age of 6 years.

Therapeutic group: antihistamines.

Cetirizine dihydrochloride, the active ingredient in these tablets, 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 N-Alergya 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 this medicine

Do not use this medicine if:

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

Special warnings about using this medicine

Before you start using N-Alergya, tell your doctor if:

- You have kidney failure. If necessary, you will take a lower dose of this medicine. Your doctor will determine your new dose.
- You have problems passing urine (like spinal cord problems or prostate or bladder problems).
- You have epilepsy or are at risk of getting convulsions.
- You are scheduled for allergy testing. Ask your doctor if you should stop taking N-Alergya for several days before testing. This medicine may affect your allergy test results.

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

Other medicines and N-Alergya
If you are taking or have recently taken other medicines, including nonprescription medications and dietary supplements, tell your doctor or pharmacist.

Using this medicine and food
You can take this medicine with or without food. Food does not affect absorption of this medicine.

Using this medicine and alcohol consumption
When used at the recommended doses no clinically significant reactions were observed between alcohol (at the blood level of 0.5 per mille (gram/liter), equivalent to one glass of wine) and cetirizine. However, there is no safety information about taking higher doses of cetirizine with alcohol. So, as with all antihistamines, it is advisable to avoid taking N-Alergya 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 have a baby, ask your doctor for advice before taking this medicine.
Do not take N-Alergya during pregnancy. Accidental use of the medicine by a pregnant woman should not produce any harmful effects on the unborn baby. Nevertheless, the medicine should only be administered if necessary and after consulting a doctor.
Cetirizine passes into breast milk. So, do not take N-Alergya if you are breastfeeding unless your doctor advises it.

Driving and using machines
Clinical studies have produced no evidence of impaired attention, alertness, and driving capabilities after taking N-Alergya at the recommended dose.

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

Important information about some of this medicine's ingredients
This medicine contains lactose. If you have been told by your doctor that you have an intolerance to certain sugars, consult your doctor before taking these tablets.

3. How to use this medicine?

Always use this medicine exactly as described in this leaflet or as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure about your dose or about how to take this medicine.

The usual dose, unless instructed otherwise by the doctor is:
Children aged 6-12 years: half a tablet twice a day in the morning and in the evening or one tablet once a day.

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

Adults and children aged 12 years and over: maximum one tablet per day.

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

If you feel sleepy or dizzy, taking half a tablet 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.

Take your tablet with a glass of liquid. You may crush/split/chew the tablet.

If you have accidentally taken a higher dose
If you think you have taken an overdose of N-Alergya, consult your doctor. Your doctor will then 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 forget to take the medicine
Do not take a double dose to make up for a forgotten tablet. If you forget to take a tablet at the usual time, take one as soon as you remember, but wait at least 24 hours before taking your next tablet.

If you stop taking this medicine
Rarely, intense itching (pruritus) and/or hives (urticaria) may return if you stop taking N-Alergya.

Do not take medicines in the dark! Check the label and dose every time you take medicine. Wear glasses if you need them.
If you have any further questions about using this medicine, consult your doctor or pharmacist.

4. Side effects

Like with all medicines, using this medicine may cause side effects in some users. Do not be alarmed by this list of side effects; you may not experience any of them.
The following side effects are rare or very rare, but you must stop taking the tablets and talk to your doctor straight away 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 (may affect up to 1 in 10 patients)

- 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 (may affect up to 1 in 100 patients)

- agitation
- paresthesia (abnormal feelings on the skin)
- abdominal pain
- pruritus (itchy skin), rash
- asthenia (extreme fatigue), malaise

Rare side effects (may affect up to 1 in 1,000 patients)

- allergic reactions, some severe (very rare)
- depression, hallucination, aggression, confusion, insomnia
- convulsions
- tachycardia (heart beating too fast)
- abnormal liver function
- urticaria (hives)
- edema (swelling)
- weight gain

Very rare side effects (may affect up to 1 in 10,000 patients)

- thrombocytopenia (low levels of blood platelets)
- tics (involuntary movements that have no function)
- syncope (fainting), dyskinesia (involuntary movements), dystonia (abnormal prolonged muscular contraction), tremor, dysgeusia (altered taste)
- blurred vision, difficulty focusing (accommodation disorder), eyes make uncontrolled circular movements
- angioedema (serious allergic reaction which causes swelling of the face or throat), rash in a specific site resulting from using this medicine
- passing urine abnormally (bed wetting, pain and/or difficulty passing urine)

Side effects whose frequency is not known (frequency has not been established yet)

- 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 you experience any side effect, if any side effect gets worse, or if you experience a side effect not mentioned in this leaflet, consult your doctor.

You can report side effects to the Ministry of Health by following the link 'Reporting Side Effects of Drug Treatment' on the Ministry of Health home page (www.health.gov.il) which links to an online form for reporting side effects. You can also use this link: https://sideeffects.health.gov.il
You can also report by email to safety@trima.co.il

5. How to store the medicine?

- Prevent poisoning! To prevent poisoning, keep this, and all other medicines, in a closed place, out of the reach and sight of children and/or infants. Do not induce vomiting unless explicitly instructed to do so by a doctor.
- Do not use the medicine after the expiry date (exp. date) which is stated on the package and blister. The expiry date refers to the last day of that month.

Storage conditions

- Store in a dry place below 25°C.

- Do not throw the medicine away via wastewater or household waste. Ask the pharmacist how to throw away this medicine (medicines you no longer use). These measures will help protect the environment.

6. Additional information

In addition to the active ingredient, this 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 contents of the pack
A round white tablet with a break line on one side. This medicine is supplied in packs of 7 and 20 tablets.
Not all pack sizes may be marketed.

Manufacturer and registration holder: Trima Israel Pharmaceutical Products Maabarot Ltd., Maabarot 4023000, Israel.

This leaflet was revised in August 2022 according to the Ministry of Health guidelines.
Registration number of the medicine in the Ministry of Health National Drug Registry: 155-16-34652-00.