

**ALLER STOP**  
**Instructions**  
**on medical use of the drug**

**Tradename:** Aller Stop.

**International nonproprietary name:** Cetirizine dihydrochloride.

**Dosage form:** Oral solution.

**Compound:** 1 ml of solution contains: Active substance:

Cetirizine dihydrochloride 1 mg;

Excipients: 70% sorbitol, glycerin, sodium benzoate, citric acid monohydrate, sodium citrate, purified water.

**Pharmacotherapeutic group:** Antiallergic agent, H1 histamine receptor blocker.

**ATX code:** R06AE07.

**Pharmacologic effect:**

*Pharmacodynamics:*

*Cetirizine* belongs to the group of competitive histamine antagonists, blocks H1 histamine receptors, and has virtually no anticholinergic and antiserotonin effects. It has a pronounced antiallergic effect, prevents the development and facilitates the course of allergic reactions. Has antipruritic and antiexudative effect. Affects the "early" stage of allergic reactions, and also reduces the migration of inflammatory cells; inhibits the release of mediators involved in the "late" stage of the allergic reaction. Reduces capillary permeability, prevents the development of tissue edema, relieves spasm of smooth muscles. Eliminates skin reactions to the introduction of histamine, specific allergens, as well as to cooling (with cold urticaria). In therapeutic doses it has virtually no sedative effect. During the course of treatment, tolerance does not develop. The effect of the drug after taking a single dose of 10 mg begins after 20 minutes (in 50% of patients), after 1 hour (in 95% of patients), and lasts for 24 hours. After discontinuation of the drug, the effect persists for up to 3 days.

*Pharmacokinetics:*

*Absorption:* after oral administration, the drug is quickly and well absorbed from the gastrointestinal tract. The maximum concentration level is determined after approximately 30 - 60 minutes. Food intake does not have a significant effect on the amount of absorption, but it prolongs the time to reach the maximum concentration (TC max) by 1 hour and reduces the value of the maximum concentration (C max) by 23%.

*Distribution:* cetirizine is approximately 93% bound to plasma proteins.

The volume of distribution (Vd) is low (0.5 l/kg).

*Metabolism:* Cetirizine is metabolized in small quantities by O- dealkylation to form an inactive metabolite. With 10-day use at a dose of 10 mg, no accumulation of the drug is observed.

*Excretion:* approximately 70% occurs by the kidneys, mainly unchanged. In addition to the kidneys, it is excreted through the intestines. The systemic clearance is about 54 ml/min. The half-life is approximately 10 hours. In children aged 6 to 12 years, the half-life decreases to 6 hours.

In case of impaired renal function (creatinine clearance below 11-31 ml/min) and in patients on hemodialysis (creatinine clearance less than 7 ml/min), the half-life increases 3 times, the total clearance decreases by 70%. Against the background of chronic liver diseases and in elderly patients when taking the drug in a dose 10 mg there is an increase in the half-life by 50% and a decrease in systemic clearance by 40%.

**Indications for use:**

- Treatment of symptoms of year-round and seasonal allergic rhinitis and allergic conjunctivitis, such as itching, sneezing, rhinorrhea, lacrimation, conjunctival hyperemia;
- Hay fever (hay fever);
- Urticaria, including chronic idiopathic urticaria;
- Quincke's edema;
- Other allergic dermatoses, including atopic dermatitis, accompanied by itching and rashes.

**Contraindications:**

- hypersensitivity to cetirizine, hydroxyzine or piperazine derivatives, as well as other components of the drug;
- severe kidney disease;
- pregnancy, lactation period;
- children under 2 years of age (efficacy and safety in young children have not been established).

**Directions for use and dosage:**

Inside, before or after meals. The drug should be taken regularly at the same time. The time of taking the drug (morning or evening) is determined depending on the individual needs of the patient.

Adults and children over 12 years of age: 10 ml 1 time per day;

Children 6-12 years old, weighing more than 30 kg: 5 ml 2 times a day;

Children 6-12 years old, weighing less than 30 kg: 5 ml once a day;

Children 2-6 years old: 5 ml once a day or 2.5 ml twice a day;

For patients with moderate renal failure (creatinine clearance 11 - 13 ml/min), patients on hemodialysis (creatinine clearance less than 7 ml/min.) and patients with impaired hepatic function, 5 ml of oral solution per day is recommended.

**Side effects:**

*From the digestive system:* dry mouth, dyspepsia.

*From the central nervous system:* headache, drowsiness, fatigue, dizziness, agitation, migraine.

*Allergic reactions:* skin rash, angioedema, urticaria, itching. The drug is usually well tolerated.

Side effects occur rarely and are transient.

**Overdose:**

With a single dose of Aller Stop in a dose of 50 mg, the following symptoms may be observed: confusion, diarrhea, dizziness, fatigue, headache, malaise, mydriasis, itching, weakness, sedation, drowsiness, stupor, tachycardia, tremor, urinary retention.

*Treatment:* immediately after taking the drug - gastric lavage or artificial induction of vomiting. It is recommended to prescribe activated carbon and carry out symptomatic and supportive therapy. There is no specific antidote. Hemodialysis is ineffective.

**Interaction with other drugs:**

When studying the drug interactions of Aller Stop with pseudoephedrine, cimetidine, ketoconazole erythromycin, azithromycin, diazepam and glipizide, no clinically significant interactions were identified. Co-administration with theophylline (400 mg/ day) leads to a decrease in the total clearance of cetirizine by 16% (the kinetics of theophylline does not change). When administered simultaneously with macrolides and ketoconazole, no changes are observed in the electrocardiogram. When using the drug in therapeutic doses, no data on interactions with alcohol were obtained (at a blood alcohol concentration of 0.5 g/l). However, you should refrain from drinking alcohol during drug therapy to avoid depression of the central nervous system.

**Special instructions:**

An objective assessment of the ability to drive vehicles and operate machinery did not reliably reveal any adverse events when taking the drug at the study dose. But, nevertheless, during the period of use of the drug, it is advisable to refrain from engaging in potentially hazardous activities that require increased concentration and speed of psychomotor reactions.

**Release form:**

Oral solution 120 ml in a bottle along with instructions for use in a cardboard box.

**Storage conditions:**

Store in a dry place, protected from light, at a temperature not exceeding 25 °C.

Keep out of the reach of children!

**Best before date:**

Indicated on the packaging. Do not use the drug after the expiration date.

**Conditions for dispensing from pharmacies:**

Over the counter.

**Made for:**

**MAXX PHARM LTD.**

**London, Great Britain**

