

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

**Tradename:** Aller Stop.

**International nonproprietary name:** Cetirizine dihydrochloride.

**Dosage form:** Film-coated tablets for oral administration.

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

**ATX code:** [R06AE07].

**Composition:** *Each film-coated tablet contains:*

10 mg cetirizine dihydrochloride;

as an excipient - lactose.

**Pharmacologic effect:**

*Pharmacodynamics:*

Aller -STOP is an antihistamine that has an antiallergic effect. A selective antagonist of histamine H1 receptors, does not cause a significant anticholinergic and antiserotonin effect. In therapeutic doses, it has virtually no sedative effect and does not cause drowsiness. The drug affects the "early" histamine-dependent stage of the allergic reaction and the "late" cellular stage, reducing the migration of eosinophils, and also reduces the expression of adhesion molecules such as ICAM-1 and VCAM-1, which are markers of allergic inflammation. Suppresses the effect of other mediators and inducers of histamine secretion, such as PAF (platelet-activating factor) and substance P; reduces histamine-induced bronchoconstriction in mild bronchial asthma, has a high inhibitory ability against skin reactions.

*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 at a dose of 10 mg, there is an increase in the half-life by 50% and a decrease in systemic clearance by 40%.

**Indications for use:**

- seasonal and chronic allergic rhinitis;
- allergic conjunctivitis;
- dermatoses that occur with itching;
- urticaria (including chronic idiopathic urticaria);
- Quincke's edema.

**Contraindications:**

- hypersensitivity to the drug;
- pregnancy and lactation;
- children under 2 years of age;
- severe renal failure (creatinine clearance less than 10 ml/min).

**Precautionary measures:**

The drug should be used with caution in patients with chronic renal failure and the elderly (possible reduction in glomerular filtration). If you have an intolerance to certain sugars, talk to your doctor before taking this medicine. Patients with rare hereditary problems of galactose intolerance, lactase deficiency or glucose-galactose deficiency If you suffer from malabsorption, you should not take Aller STOP tablets. Taking the drug must be stopped no later than 48 hours before skin diagnostic allergy tests are performed to prevent erroneous results. Use with caution in patients with a predisposition to urinary retention, as cetirizine increases the risk of its development.

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.

**Mode of application:**

For oral administration. The duration of the course of treatment is determined by the doctor. Sometimes an initial dose of 5 mg may be sufficient to achieve a therapeutic effect.

It is recommended to take the drug:

*Children aged 2 to 6 years: 2.5 mg 2 times a day.*

*Children aged 6 to 12 years: 5 mg 2 times a day.*

*Adults and adolescents over 12 years of age: 10 mg 1 time per day.*

**Side effects:**

From the digestive system: dry mouth, rarely – dyspeptic disorders;

From the side of the central nervous system: mild and rapidly passing drowsiness, headache, dizziness, and in some cases agitation are possible;

Allergic reactions: very rarely - skin manifestations, angioedema.

And also possible: thrombocytopenia, leukopenia, agranulocytosis, difficulty urinating, urinary retention, dysuria, hepatobiliary disorders.

The drug is generally well tolerated. Side effects occur rarely and are usually mild and transient.

**Storage conditions:**

Store at a temperature not exceeding 25 °C out of the reach of children.

The drug should not be used after the expiration date.

**Release form:**

Tablets 10 mg, pack of 20 tablets.

**Vacation conditions:**

Without a doctor's prescription.

**Made for:**

**MAXX PHARM LTD.  
London, Great Britain**

