**LAZOLMAX**
**Instructions**
**on medical use of the drug**

**Trade name:** Lazolmax.
**International nonproprietary name:** Ambroxol + cetirizine.
**Dosage form:** Syrup for oral administration.
**Composition:** *5 ml syrup contains:*
Ambroxol hydrochloride BP 15 mg;
Cetirizine hydrochloride BP 2.5 mg.
**Description:**
Transparent or almost transparent, colorless or almost colorless, slightly viscous liquid with the smell of wild berries.
**Pharmaco -therapeutic group:**
Expectorant, mucolytic, antihistamine.
**ATX code:** R05CB06.
**Pharmachologic effect:**
*Pharmacodynamics:*
*Ambroxol:* Studies have shown that ambroxol, the active ingredient in the drug, increases secretions in the respiratory tract. It enhances the production of pulmonary surfactant and stimulates ciliary activity. These effects lead to increased mucus flow and transport (mucociliary clearance). Increasing mucociliary clearance improves sputum discharge and relieves cough.
*Cetirizine* is an antiallergic drug. Cetirizine is a selective H1 receptor antagonist that does not have significant anticholinergic and antiserotonin effects. Cetirizine does not penetrate the BBB. Cetirizine inhibits the early phase of the allergic reaction, and also reduces the migration of inflammatory cells, such as eosinophils, and suppresses the release of mediators that are involved in the late allergic reaction.
Cetirizine significantly reduces the hyperactivity of the bronchial tree, which occurs in response to the release of histamine in patients with bronchial asthma. These effects of the drug are not accompanied by a central effect, as confirmed by psychometric tests and ECG data.
*Pharmacokinetics*
*Ambroxol* is very well absorbed after oral administration, C max in the blood plasma is reached after 0.5-3 hours. Plasma protein binding is 80%. Penetrates through the blood-brain barrier, placental barrier, and is excreted in breast milk. Metabolized in the liver to form dibromanthranilic acid and glucuronic acid conjugates T ½ is 1 hour. Excreted by the kidneys: 90% - in the form of water-soluble metabolites, 5% - unchanged.
*Cetirizine* is rapidly absorbed when taken orally, with an elimination half-life of 7.9 ± 1.9 hours in adults. Cetirizine and its metabolites are mainly excreted in the urine.
*Pharmacokinetics in special clinical cases:* T ½ increases in severe chronic renal failure, does not change in case of impaired liver function.
**Indications for use:**
- diseases of the respiratory tract with the release of viscous sputum;
- bronchial asthma with difficulty in sputum discharge;
- acute and chronic bronchitis;
- pneumonia;
- bronchiectasis;
- chronic obstructive pulmonary diseases.

**Contraindications:**
- hypersensitivity to the components of the drug;
- severe kidney disease.

*With caution* for chronic pyelonephritis of moderate and severe severity, and for renal failure (dosage regimen adjustment is required).

**Directions for use and dosage:**
The drug is prescribed orally, during meals, with a small amount of liquid. For treatment lasting more than 7–14 days, the dose is reduced by half. It is not recommended to use without medical prescription for more than 4-5 days. During treatment, it is necessary to drink a lot of liquid (juices, tea, water), as it enhances the mucolytic effect of the drug. It is not recommended to take the drug late in the evening or at night. Recommended dosage:

- children under 2 years old - 2.5 ml 2 times a day;
- children from 2 to 5 years old - 2.5 ml 3 times a day;
- children over 5 years old - 5 ml 2-3 times a day.

**Side effect:**
*Gastrointestinal disorders*
Often (1.0-10.0%) - nausea, decreased sensitivity in the mouth or pharynx;
Uncommon (0.1-1.0%) - dyspepsia , vomiting, diarrhea, abdominal pain, dry mouth;
Rarely (0.01-0.1%) - dry throat.
*Immune system disorders, damage to the skin and subcutaneous tissues*
Rarely (0.01-0.1%) - rash, urticaria; anaphylactic reactions (including anaphylactic shock)*, angioedema", itching*, hypersensitivity.
*Nervous system disorders*
Often (1.0-10.0%) - dysgeusia (impaired sense of taste).
* - these adverse reactions were observed with widespread use of the drug; with a 95% probability, the frequency of these adverse reactions is uncommon (0.1%-1.0%), but possibly lower; The exact frequency is difficult to estimate as they have not been reported in clinical studies.
**Overdose:**
Specific symptoms of overdose in humans have not been described.
There have been reports of accidental overdose and/or medical error resulting in symptoms of known side effects of Lazolmax: nausea, dyspepsia, diarrhea, vomiting, abdominal pain. In this case, there may be a need for symptomatic therapy.
*Treatment*: artificial vomiting, gastric lavage in the first 1-2 hours after taking the drug, symptomatic therapy.
**Interaction with other drugs:**
No clinically significant, undesirable interactions with other drugs have been reported. Increases the penetration of amoxicillin, cefuroxime , erythromycin into the bronchial secretions.
**Special instructions:**
It should not be combined with antitussives that make it difficult to remove sputum. There are isolated reports of severe skin lesions, such as Stevens-Johnson syndrome and toxic epidermal necrolysis, coinciding with the prescription of expectorants containing ambroxol hydrochloride.
In most cases, they can be explained by the severity of the underlying disease and/or concomitant therapy. In patients with Stevens -Johnson syndrome or toxic epidermal necrolysis in the early phase may cause fever, body pain, rhinitis, cough and sore throat. With symptomatic treatment, it is possible to erroneously prescribe anti-cold medications. If new lesions of the skin and mucous membranes appear, it is recommended to stop treatment with a drug containing ambroxol and immediately seek medical help.
If renal function is impaired, Lazolmax should be used only on the recommendation of a doctor.
**Effect of the drug on the ability to drive vehicles and machinery:**
There were no cases of the drug affecting the ability to drive vehicles and machinery. Studies on the effect of the drug on the ability to drive vehicles and engage in other potentially hazardous activities that require increased concentration and speed of psychomotor reactions have not been conducted.
**Release form:**
Syrup 15 mg/5ml.
100 ml in amber or brown glass bottles with a child-safe plastic screw cap with thread and tamper evident. The bottle is placed in a cardboard box with instructions for use.
**Storage conditions:**
At a temperature not higher than 25 °C.
Keep out of the reach of children.
**Best before date:**
3 years. Do not use after the expiration date stated on the package.
**Conditions of release from pharmacies:**
**According to a doctor's prescription**

**Made for:**
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