LAZOLMAX
Instructions
on medical use of the drug

Tradename: Lazolmax.
International nonproprietary name: Ambroxol + Cetirizine.
Dosage form: Syrup for oral administration.
Composition: *5 ml syrup contains:*
Active substance:
Ambroxol hydrochloride BP 30 mg;
Cetirizine hydrochloride BP 5 mg.
Description:
Transparent or almost transparent, colorless or almost colorless, slightly viscous liquid with a strawberry odor.
Pharmacotherapeutic group: Expectorant, mucolytic, antihistamine
ATX code: R05CB06.
Pharmachologic effect:
Pharmacodynamics:
Ambroxol: Studies have shown that ambroxol 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;
- childhood;
- fructose intolerance;
- pregnancy and lactation (breastfeeding).

With caution for chronic pyelonephritis of moderate and severe severity, for renal failure (correction of the dosage regimen is required), for elderly people (due to a possible decrease in glomerular filtration in this category of patients).
LAZOLMAX syrup (30 mg/5 ml) contains 5 g of sorbitol based on the maximum recommended daily dose (20 ml). Patients with rare hereditary fructose intolerance should not take this drug.
Pregnancy and lactation:

Ambroxol penetrates the placental barrier. Animal experiments have not revealed direct or indirect adverse effects on pregnancy, embryonic, prenatal and postnatal development and childbirth. Comprehensive clinical studies after 28 weeks of pregnancy found no evidence of a negative effect of the drug on the fetus.
However, normal precautions must be taken when using the medicine during pregnancy. It is especially not recommended to take LAZOLMAX in the first trimester of pregnancy.
Ambroxol can be excreted in human milk. Despite the fact that no undesirable effects were observed in breast-fed children, it is not recommended to use LAZOLMAX syrup during lactation.

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 **.**
Adults and children over 12 years old: 5 ml 3 times a day;

Side effect:

Gastrointestinal disorders
Often (1.0-10.0%) - nausea;
Uncommon (0.1 -1.0%) - heartburn, dyspepsia, vomiting, diarrhea, pain in the upper abdomen; dry mouth and throat*, decreased sensitivity in the mouth or throat*;
Immune system disorders, damage to the skin and subcutaneous tissues;
Rarely (0.01 -0.1%) - skin rash, urticaria; anaphylactic reactions (including anaphylactic shock)*, angioedema*, itching* and other allergic reactions*.
Nervous system disorders
Dysgeusia * (impaired sense of taste).
* only isolated reports of these adverse reactions were noted with widespread use of the drug, but the connection with taking the drug LAZOLMAX has not been proven; the frequency of these rare events is difficult to estimate.

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, heartburn, dyspepsia, vomiting, upper 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. The sorbitol contained in the syrup may have a mild laxative effect.
In patients with severe skin lesions such as Stevens -Johnson syndrome or toxic epidermal necrolysis - in the early phase, fever, body pain, rhinitis, cough and sore throat may appear. During symptomatic treatment, it is possible to erroneously prescribe mucolytic agents such as ambroxol hydrochloride. There are isolated reports of the detection of Stevens -Johnson syndrome and toxic epidermal necrolysis coinciding with the prescription of the drug; however, there is no causal relationship with the drug.
If the above syndromes develop, it is recommended to stop treatment and immediately seek medical help.
If kidney 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 30 mg/5 mg. 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:

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

Best before date:

Indicated on the packaging.

Do not use after the expiration date stated on the package.
Conditions of release from pharmacies:
According to a doctor's prescription.

Made for:
MAXX PHARM LTD.
London, Great Britain