LAMBROTIN

Instructions for the medicinal product

Trade name: Lambrotin.
International Nonproprietary Name: Ambroxol + Ceterizine.
Dosage form: Tablets.
Composition: Each uncoated tablet contains:
Ambroxol Hydrochloride BP 30 mg;
Cetirizine Hydrochloride BP 5 mg.
Pharmacotherapeutic group: Mucolytics and antihistaminic drug.
ATC Classification: R05CB06.
Pharmacologic property:
Pharmacodynamics:
Ambroxol (group of benzilamides) belongs to secretolitical and secretomotoric medicinal products. It possesses expressed expectorant effect. Mechanism of action of the medicinal product is stipulated by stimulation of serous cells of tonsils of bronchial tubes' mucous membrane, increasing of mucous secretion content and changing of correlation of serous and mucous components of phlegm, breached under pathological processes in lungs. Under this hydrolyzing ferments activate and releasing of lizosoms from Clark's cells strengthens, that causes decreasing of viscosity of phlegm. Ambroxol increases content of surfactant in lungs, which is dealt with strengthening of synthesis of the last and secretion in alveolar pneumocytes, and also with breach of its disintegration. The medicinal product increases mucociliar transport of phlegm. It suppresses coughing insignificantly. The medicinal product does not cause immense creating of secretion, reduces spastic hyperactivity of bronchial tubes- one of the main factors of developing of bronchial asthma under allergy.
Cetirizine, a human metabolite of hydroxyzine, is a potent antihistamine, selective H1 receptor antagonist. The histamine-mediated 'early' phase of the allergic reaction is inhibited by cetirizine, which also reduces the migration of inflammatory cells and the release of mediators associated with the 'late' allergic responses. Effects on other receptors are negligible and consequently cetirizine is unlikely to cause undesirable anti-cholinergic and antiserotonin effects.
Pharmacokinetics:
Ambroxol is rapidly absorbed (70-80%) after oral administration. The time to reach peak plasma concentration is approximately 2 hours. The distribution half-life of ambroxol is around 1.3 hours. Excretion is primarily via the kidneys. Renal clearance (rate) is approximately 53 ml/minute; approximately 5-6% of a dose is excreted unchanged in the urine.
Cetirizine is rapidly absorbed from the gastrointestinal tract; absorption is not reduced by food, though the rate may be decreased slightly. Cetirizine is mainly excreted unchanged in the urine (approximately 70% over 5 days compared with 10% in the faeces). The half-life is increased in renal dysfunction: half lives of 19 and 21 hours in patients with mild to moderate renal impairment respectively have been reported. Cetirizine binds strongly to plasma proteins.
Indications for use:
Respiratory tract diseases with discharge of viscous mucus:
- Bronchial asthma with difficulty sputum discharge;
- Acute and chronic bronchitis;
- Pneumonia;
- Bronchoectatic disease;
- Chronic obstructive pulmonary disease.
- **Contraindications:**
- Known hypersensitivity to the product;
- Gastric ulceration;
- Chronic kidney disease;
- Due to the high active-substance content, Lambrotin is not suitable for children under 6 years;
- Pregnancy and lactation.

Precaution:
Caution is necessary when bronchomotoric function is impaired. Patients with hepatic and renal insufficiency should take it with caution. Lambrotin should not be given with cough suppressants, as a dangerous increase of bronchial secretion occur.
Pregnancy and Nursing Mother:
Ambroxol has not been shown to have any teratogenic or toxic effects on the foetus. However, there are no adequate and well-controlled studies of levocetirizine in pregnant women. Hence, Lambrotin should not be used during pregnancy.
Since levocetirizine is expected to be excreted in breast –milk, the combination is not recommended during lactation.
Dosage and directions for use:
Oral use, with meals and drinking a small amount of liquid.
Adults and adolescents over 12 years: 1 tablet 2 times a day.
Children aged 6 to 12 years: ½ tablet 2 times a day.
Not recommended for use without a doctor's prescription for more than 4-5 days.
During treatment, need to drink plenty of fluids (juice, tea, water), as it increases the mucolytic effect of the drug.
Side-effects:
At the recommended doses, ambroxol is well tolerated. Nausea, headache and gastrointestinal disorders have been observed rarely. Other toxic effects include skin irritation, eye irritation and respiratory tract irritation. Ingestion of large doses may cause gastrointestinal tract irritation with decreased motility or constipation, ulceration or bleeding from the stomach or duodenum, and peritonitis. It may affect behaviour/CNS (tremor, convulsions, ataxia and somnolence), respiration (dyspnoea, respiratory stimulation), the liver, blood (changes in white blood cell count) and the urinary system. Occasional gastrointestinal side effects may occur but these are normally mild.
Overdose:
Symptoms: nausea, vomiting, diarrhea, dyspepsia, drowsiness, lethargy, weakness, headache, tachycardia, irritability, urinary retention, fatiguability (when taken of cetirizine in a daily dose of 50 mg).
Treatment: artificial vomiting, gastric lavage should be performed within 1-2 hours after drug ingestion, activated charcoal.
Drug interaction*:*
Cetirizine: No interaction studies have been performed with levocetirizine (including no studies with CYP3A4 inducers); studies with the racemate compound, cetirizine, demonstrated that there were no clinically relevant adverse interactions (with pseudoephedrine, cimetidine, ketoconazole, erythromycin, azithromycin, glipizide and diazepam). A small decrease in the clearance of cetirizine (16%) was observed in a multiple-dose study with theophylline (400 mg once a day), while the disposition of theophylline was not altered by concomitant cetirizine administration. The extent of absorption of levocetirizine is not reduced with food, although the rate of absorption is decreased. In sensitive patients, the simultaneous administration of cetirizine or levocetirizine and alcohol or other CNS depressants may result in CNS effects, although it has been shown that the racemate cetirizine does not potentiate the effect of alcohol.
Ambroxol:
Simultaneous use of ambroxol and antibiotics (amoxicillin, cefuroxime, erythromycin, doxycycline) results in an increase of concentration of the antibiotics in the lung tissue.
Concomitant use with antitussive agents, e.g. codeine should be avoided, because they may inhibit cough reflex.
Cautions:
Always disclose any of the following information to your physician before use:
- If you are pregnant, trying to conceive, or breastfeeding;
- Any allergies you have;
- Any illnesses or conditions you have;
- Any supplements, vitamins, or herbal products;
- Any other drugs or medication you are taking.

Should be cautiously used in patients with increased sputum secretion and disorders of secretion discharge (such as the rare malignant cilia syndrome) due to a risk of airway obstruction because of impaired bronchi motor function and a large quantity of bronchial secretions.
In case of renal and/or liver disease the dose is reduced or the interval between the drug intakes is extended.
In case of severe renal insufficiency ambroxol metabolite accumulation is expected.
Should be used cautiously in patients with peptic ulcer disease history as mucolytic products may weaken gastric mucosal barrier.
There are very rare reports of severe skin reactions (e.g. Stevens-Johnson syndrome and Lyell's syndrome) occurrence during of Lambrotin administration. In case of changes of skin and mucous membranes, Lambrotin administration should be immediately discontinued and the appropriate treatment should be carried out.
Effects on ability to drive and use machines:
Drug administration has no influence on the ability to drive and use machines.
Presentation:
10 tablets in each blister alu alu, 2 blisters (20 tablets) with package leaflet in the carton pack.
Storage:
Keep in dry place protected from light at a temperature below 25°C. Keep out of reach of children.
Shelf life:
Labeled. Do not use after expiry date.
Distribution Condition:
Non-prescribed medicine.

BELINDA

Manufactured for:
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