LAMBROTIN

Instructions for the medicinal product

Trade name: Lambrotin.
International Nonproprietary Name: Ambroxol+ Cetirizine.
Dosage form: Syrup.
Composition:
Lambrotin 15: each 5 ml contains:
Ambroxol Hydrochloride BP 15 mg;
Cetirizine Hydrochloride BP 2,5 mg.
Lambrotin 30: each 5 ml 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:
- drug hypersensitivity;
- chronic kidney disease;
- pregnancy and lactation.

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.
Dosage and directions for use:
For oral use only.
For children it is recommended to take Lambrotin 15 (ambroxol 15 mg /5 ml) in following doses:
Children up to 2 years: 2.5 ml syrup 2 times daily.
Children 2 - 5 years: 2.5 ml syrup three times daily.
Children over 5 years: 5 ml syrup two-three times daily.
For adults it is recommended 10 ml of Lambrotin 30 (ambroxol 30 mg /5 ml) 2-3 times a day.
In the treatment for longer than 7-14 days the dose is reduced twice.
It is not recommended to use more than 4-5 days.
Drink plenty of fluids during the treatment (juice, tea, water).
Side-effects:
Lambrotin syrup is usually well tolerated. Rarely hypersensitivity reactions, weakness, headache, stomachalgia, fullness in the stomach, nausea, vomiting, indigestion. If these side effects occur, should discontinue use of the drug.
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, administered activated charcoal.
Drug interaction:
No evidence of interactions with psuedoephedrine, antipyrine, ketoconazole, erythromycin, azithromycin, diazepam and cimetidine has been reported. Theophylline decreases the clearance of cetirizine although the disposition of theophylline is not affected. In common with other antihistamines it is recommended that excessive alcohol consumption should be avoided. Concurrent use of cetirizine with other CNS depressants should also be avoided as reduction in alertness and impairment of performance may occur.
Cautions:
Lambrotin should be given with care to patients suffering from peptic ulcer.
Presentation:
Plastic bottle of 100 ml syrup in carton box, with instruction for use.
Storage:
Keep in dry place protected from light at a temperature below 30°C. Keep out of reach of children.
Shelf life:
Labeled. Do not use after expiry date.
Distribution Condition:
Non-prescribed medicine.

BELINDA

Manufactured for:
Branch of Apteki 36.6 Ltd.,
Kabul, Afghanistan
Manufactured by:
LARK LABORATORIES (INDIA) LTD,
SP-1192 E, Phase-IV,
RIICO Industrial Area,
Bhiwadi-301019, Alwar,
Rajasthan, India