

Acebrophylline Capsules

VELOAIR®

Other rarely reported adverse events include headache, occasional numbness in arm, insomnia, tachycardia, fatigue, hypertension, albuminuria, glycosuria, hypotension and occasionally hyperglycemia.

Overdosage:

There is no clinical data available on overdosage with acebrophylline. However, if overdosage with acebrophylline occurs, it can cause ventricular tachycardia and cardiac arrhythmia.

In case of overdosage, patients should be given active charcoal with laxative and emesis should be induced. Ventilation should be ensured, and respiratory rate and blood pressure should be closely monitored. If acebrophylline treatment is required again even after an overdose, the treatment should begin after complete recovery, using smaller doses.

Incompatibilities:

None.

Storage:

Store in a cool and dry place. Protect from light and moisture.

Keep out of reach of children.

Presentation: Blister of 10 capsules

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TM TRADEMARK UNDER REGISTRATION

Manufactured by:
TIRUPATI MEDICARE LIMITED
Nahan Road, Paonta Sahib,
Distt. Sirmour -173 025 (H.P.)



Marketed by:
SAVA MEDICA LIMITED
Viman Nagar, Pune -14, INDIA.
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70 mm

70 mm

and absorbed in the intestine, reaching optimal concentrations of ambroxol within 2hrs and of theophylline-7-acetic acid after 1 hr. The plasma half life varies from 4 to 9 hrs after oral administration. The drug is metabolized in the liver and eliminated renally.

Indications:

Acebrophylline capsule is indicated for the treatment of adult patients with chronic obstructive pulmonary disease (COPD) and bronchial asthma.

Dosage and administration:

The usually recommended dose of acebrophylline capsule for adults is one capsule twice daily.

Elderly: Dosage should be adjusted if required in elderly patients.

Pediatric use: Acebrophylline capsules are not recommended in children.

Contra-indications:

- Hypersensitivity to ambroxol, acebrophylline, theophylline or any other xanthine derivative.
- Patients suffering from acute myocardial infarction.
- Patients with hypotension, hemodynamic instability and arrhythmias.
- Patients with renal disease or liver disorder.

Warnings and Precautions:

Caution is advised in patients with cardiac insufficiency, other cardiovascular diseases, coronary artery disease, hypertension and preexisting arrhythmia's.

Acebrophylline capsule should be carefully administered in patients with a history of epilepsy and hyperthyroidism. Care should be taken in patients having gastrointestinal disorders like duodenal ulcer. Caution is advised in patients with severe respiratory disease.

Careful monitoring is advised in elderly patients, those consuming alcohol, or smoking, patients with renal and/or hepatic impairment, those with vascular occlusion or congestive heart failure, since these may lead to higher plasma levels of the drug. A lower dose may be required under these conditions.

Composition:

Each hard gelatin capsule contains:

Acebrophylline 100mg
Excipients q.s.

Approved colours used in empty capsule shells.

Clinical Pharmacology:

Acebrophylline, chemically ambroxol theophylline-7-acetate (ambroxol acephyllinate), is a compound with both mucolytic and bronchodilator properties.

Mechanism of action:

Theophylline-7-acetate, as with other xanthinic derivatives, has a bronchodilator effect due to inhibition of the intracellular phosphodiesterases, followed by an increase of adenosine monophosphate cyclic levels, which promote the relaxation of bronchial muscles.

Ambroxol modifies the mucous gel phase of secretions by decreasing the viscosity and increasing the serous gel phase. It increases the mucociliary clearance by stimulating cilia motility. Acebrophylline inhibits phospholipase A and phosphatidylcholine leading to lesser production of the powerful pro-inflammatory substances like leukotrienes and tumour necrosis factor. By inhibiting the synthesis and release of these inflammatory mediators, acebrophylline reduces inflammation, a key factor in airway obstruction, especially in chronic forms.

Pharmacokinetics:

In healthy volunteers, given 200mg oral acebrophylline, the two components of the molecule ambroxol and theophylline-7-acetic acid are released in the stomach

Prolonged use may lead to increased plasma levels of the drug.

Pregnancy & lactation

Acebrophylline is not recommended in pregnancy as well as during parturition.

The safety of acebrophylline is not established during lactation period. Hence the use of acebrophylline is not advisable in nursing mothers.

Drug Interactions:

The plasma concentration of acebrophylline may be increased by concurrent administration of erythromycin, cephalixin, oxytetracycline, oligomycin, lincomycin, cimetidine, clindamycin, allopurinol, quinolines, anticoagulants, etc. if concomitant use is essential, the dose of acebrophylline should be reduced.

The concomitant use of acebrophylline and furosemide can potentiate diuresis, white concomitant use of acebrophylline with reserpine can cause tachycardia.

Acebrophylline plasma concentration may be decreased in patients by coadministration with drugs like phenytoin and barbiturates and in patients who smoke.

It is advisable not to use acebrophylline with any other theophylline derivatives, ambroxol derivative or central nervous system stimulants.

Caution is advisable when acebrophylline is used with ephedrine, sympathomimetics and any other bronchodilator.

Side effects:

Transient nausea and dizziness may occur on taking this drug, but these effects are reversible. On cessation of therapy, these symptoms automatically disappear.

The commonly reported adverse effects with acebrophylline include abdominal discomfort, stomach/abdominal distention, vomiting, abdominal pain diarrhea, constipation, heart burn, loss of appetite, esophageal bleeding, rashes, urticaria, itching, drowsiness, difficulty in breathing, leukocytosis, and nasal inflammation. If chills and fever occur the drug should be immediately discontinued.