

XANILAX SR 200

For the use of a Registered Medical Practitioner or a Hospital or a Laboratory Only

Abbreviated Prescribing information for XANILAX SR [Acebrophylline SR Tablets 200 mg]

[Please refer the complete prescribing information available at www.torrentpharma.com]

PHARMACOLOGICAL PROPERTIES

MECHANISM OF ACTION: Theophylline-7-acetate 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. It increases the mucociliary clearance by stimulating cilia motility, as ambroxol modifies the mucous gel phase of secretions by decreasing the viscosity and increasing the serous gel phase. 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.

INDICATIONS: For the treatment of adult patients with chronic obstructive pulmonary disease (COPD) and bronchial asthma.

DOSAGE AND ADMINISTRATION: For COPD and bronchial asthma (Adults): Consider administration of 200 mg of Acebrophylline, once daily. Acebrophylline can be preferably taken after meals to avoid GI discomfort.

CONTRAINDICATION: Hypersensitivity to ambroxol, acebrophylline, theophylline or any other xanthine derivative. Patients suffering from acute hemodynamic instability and arrhythmias. Patients with renal disease or liver disorders.

WARNINGS & PRECAUTIONS: Careful monitoring is recommended for patients with congestive heart failure, chronic alcoholism, hepatic dysfunction, or viral infections. Caution should be exercised in patients with cardiac arrhythmias, other cardiovascular diseases, hyperthyroidism or hypertension, gastric and duodenal ulceration, or convulsive disorders. Patients with hepatic and renal insufficiency should take it with caution.

DRUG INTERACTIONS: The following reduce clearance and a reduced dosage may therefore be necessary to avoid side effects: allopurinol, cimetidine, ciprofloxacin, corticosteroids, diltiazem, erythromycin, furosemide, isoprenaline, oral contraceptives, thiabendazole and verapamil, doxycycline, amoxicillin etc. Xanthine can potentiate hypokalaemia resulting from beta2-agonist therapy, steroids, diuretics and hypoxia. Particular caution is advised in severe asthma. It is recommended that serum potassium levels are monitored in such situations.

ADVERSE REACTIONS: Abdominal discomfort, stomach/ abdominal distension, vomiting, abdominal pain, constipation, heart burn, loss of appetite, esophageal bleeding, rashes, urticaria, itching, drowsiness, difficulty in breathing, leukocytosis, nasal inflammation, headache, occasional numbness, insomnia, tachycardia, fatigue, hypertension, albuminuria, glycosuria, hypotension and occasionally hyperglycemia.

MARKETED BY:

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(Additional information is available on request)