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

XANILAX

(Acebrophylline SR Tablets 200mg)

COMPOSITION

Each film coated sustained release tablet contains:
Acebrophylline..... 200 mg
Excipients..... q.s.
Colour: Titanium Dioxide I.P.

DOSAGE FORM

Film coated sustained release tablet.

INDICATION

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

DOSE AND METHOD OF 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.

CONTRAINDICATIONS

While the two components of acebrophylline have generally been found to be safe in earlier studies, the following contraindications have to be noted:

- 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

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.

Xanthines can potentiate hypokalaemia resulting from $beta_2$-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.
No clinically relevant unfavourable interactions with other medications have been reported.

UNDESIRABLE EFFECTS

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

The commonly reported adverse effects with acebrophylline include abdominal discomfort, stomach/abdominal distension, 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 fevers occur, the drug should be immediately discontinued.

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

PHARMACODYNAMIC AND PHARMACOKINETIC PROPERTIES

Pharmacodynamics

Acebrophylline is a compound which has been found to act as a bronchodilating, mucoregulating and anti-inflammatory drug due to its components theophylline- 7-acetate and ambroxol.

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 A2 and phosphatidylcholine leading to lesser production of the powerful pro-inflammatory substances like leukotrienes and tumor 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

After oral administration of acebrophylline, the two components of the molecule ambroxol and theophylline-7-acetic acid are released in the stomach 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.

PREGNANCY, FERTILITY AND LACTATION

Pregnancy

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

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

OVERDOSAGE
Nausea, vomiting (which is often severe), epigastric pain and haematemesis. Pancreatitis if abdominal pain persists. Restlessness, hypertonia, exaggerated limb reflexes and convulsions. Tachycardia is common. Symptomatic treatment should be provided.

EXPIRY DATE
Do not use later than the date of expiry.

PACKAGING INFORMATION
Blister (ALU-ALU) of 10 Tablets.

STORAGE AND HANDLING INSTRUCTIONS
Store below 30°C, Protect from light and moisture. Swallow whole tablet, do not crush or chew.

MARKETED BY


TORRENT PHARMACEUTICALS LTD.
Torrent House, Off Ashram Road,
Ahmedabad-380 009, INDIA

IN/XANAX 200mg/MAR-16/01/PI