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

XANILAX SR 200

1. Generic Name

Acebrophylline SR Tablets 200 mg

2. Qualitative and quantitative Composition:

Each film coated sustained release tablet contains

Acebrophylline..... 200 mg

Excipients..... q.s.

Colour: Titanium Dioxide I.P.

The excipients used are Hydroxy Propyl Methyl Cellulose, Microcrystalline Cellulose, Sodium Lauryl Sulphate, Purified Talc, Magnesium Stearate, Colloidal Silicon Dioxide, Isopropyl Alcohol, Methylene Dichloride, Polyethylene Glycol, Talcum, Itanium Dioxide.

3. Dosage form and strength

Dosage form: Sustained Release Tablet.

Strength: 200 mg

4. Clinical particulars

4.1. Therapeutic indication

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

4.2. Posology 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.

4.3. 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.

4.4. Special warnings and precautions for use

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.

4.5. Drugs interactions

The following reduce clearance and a reduced dosage may therefore be necessary to avoid sideeffects: allopurinol, cimetidine, ciprofloxacin, corticosteroids, diltiazem, erythromycin, furosemide, isoprenaline, oral contraceptives, thiabendazole and verapamil, doxycycline, amoxicillin etc.

Xanthines 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.

No clinically relevant unfavourable interactions with other medications have been reported.

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.

4.6. Use in special populations (such as pregnant women, lactating women, paediatric patients, geriatric patients etc.)

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.

4.7. Effects on ability to drive and use machines.

Not Available

4.8. 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.

Reporting of adverse reactions

Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Report suspected adverse reactions via any point of contact available at www.torrentpharma.com

4.9. Overdose

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.

5. Pharmacological properties

5.1. 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.

5.2. Pharmacodynamic properties

Acebrophylline is a compound which has been found to act as a bronchodilating, mucoregulating and anti-inflammatory drug due to its component's 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.

5.3. Pharmacokinetic properties

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.

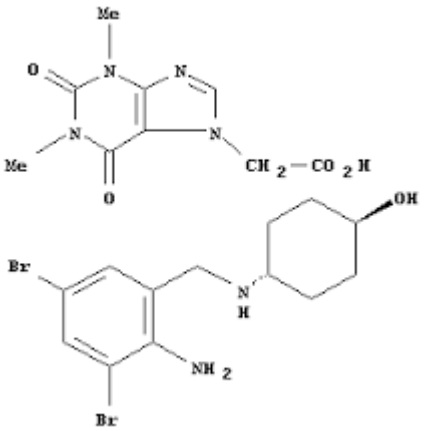
6. Nonclinical properties

6.1. Animal Toxicology or Pharmacology

Not Available

7. Description

Acebrophylline is trans-4-[[(2-Amino-3,5-dibromophenyl) methyl]amino]-cyclohexanol Mono(1,2,3,6-tetrahydro-1,3-dimethyl-2,6-dioxo-7H-purine-7-acetate). The molecular formula is $C_{22}H_{28}Br_2N_6O_5$, and the molecular weight is 616.3. The chemical structure of Acebrophylline is:



XANILAX SR 200 are White coloured, round shaped, biconvex, film coated sustained release tablets having both sides plain. The excipients used are Hydroxy Propyl Methyl Cellulose, Microcrystalline Cellulose, Sodium Lauryl Sulphate, Purified Talc, Magnesium Stearate, Colloidal Silicon Dioxide, Isopropyl Alcohol, Methylene Dichloride, Polyethylene Glycol, Talcum, Itanium Dioxide.

8. Pharmaceutical particulars

8.1. Incompatibilities

Not applicable

8.2. Shelf-life

Do not use later than date of expiry.

8.3. Packaging information

XANILAX SR is available in Blister of 10 Tablets.

8.4. Storage and handing instructions.

Store below 30°C, Protect from light and moisture.

The table should be Swallow whole & not to be chewed or crushed.

9. Patient Counselling Information

Ask the patients to inform the treating physicians in case of any of the below:

- Have any allergies.
- Have kidney or liver problems.
- Are pregnant or plan to become pregnant.
- Are breastfeeding or plan to breastfeed.
- Have any serious illness.
- Are taking any medicines (prescription, over the counter, vitamins, or herbal products)

10. **Details of manufacturer**

    Revenbhel Biotech

    EPIP SIDCO Kartholi,

    Bari-Brahmana, Jammu - 181133

11. **Details of permission or licence number with date**

    Mfg. Licence No.: JK/01/11-12/192 issued on 29.07.2015.

12. **Date of revision**

    Feb-2026

MARKETED BY

TORRENT PHARMACEUTICALS LTD.

IN/XANILAX SR 200 mg/Feb-2026/03/PI