Acebro™
(Acebrophylline)

1. NAME OF THE PRODUCT
Acebro™ (Acebrophylline) Syrup 10mg/ml

2. QUALITATIVE AND QUANTITATIVE COMPOSITION
Acebro™ Syrup 10mg/ml
Each ml contains:
Acebrophylline MS.....10mg

3. PHARMACEUTICAL FORM
Syrup

Appearance: Clear colorless to slightly colored liquid.

4. CLINICAL PARTICULARS
4.1. THERAPEUTIC INDICATIONS:
Bronchodilator in the symptomatic treatment of bronchopulmonary diseases with bronchial spastic component.

4.2. POSOLOGY AND METHOD OF ADMINISTRATION:
Dosage:
Paediatric population:
Children from 1 to 6 years: 2.5ml of syrup twice a day.
Children from 6 to 12 years: 5ml of syrup twice a day.
Adults: 10ml of syrup twice a day.
Method of administration:
For oral use.

4.3. CONTRAINDICATIONS:
- Hypersensitivity to Acebrophylline or other xanthine derivatives or to any of the excipients.
- Acute myocardial infarction.
- Hypotensive conditions.
- Severe hepatic and /or renal alteration.
- Breast-feeding.

4.4. SPECIAL WARNINGS AND PRECAUTIONS FOR USE:
Although Acebrophylline has not shown toxic phenomena during experimental tests, it should be noted that the toxic effects of xanthine derivatives are usually

linked to excessively high serum levels. Even at the recommended doses, blood levels of Acebrophylline may be higher than average due to slowed plasma clearance. In this regard, it should be noted that numerous factors can reduce theophylline clearance; among these, age, alcoholism, congestive heart failure, chronic obstructive lung disease, concomitant infections, liver and/or kidney dysfunction, concomitant administration of erythromycin, TAO, lincomycin, clindamycin and cimetidine. Cigarette smoking reduces the plasma half-life of theophylline; therefore, by analogy with theophylline, smokers may require higher doses of the drug. Theophylline should not be administered simultaneously with other xanthine preparations and caution is required when combining theophylline with ephedrine or other bronchodilator sympathomimetics. The product should be administered with caution in the elderly, younger children, heart patients, hypertensive patients and in patients with severe hypoxemia, hyperthyroidism, chronic cor pulmonale, congestive heart failure, peptic ulcer, liver and/or kidney disease. Cases of serious skin reactions such as erythema multiforme, Stevens-Johnson syndrome (SJS) / toxic epidermal necrolysis (TEN) and acute generalized exanthematous pustulosis (AGEP) have been reported in association with the administration of ambroxol-containing drugs, such as Acebrophylline. If symptoms or signs of progressive skin rash (sometimes associated with blistering or mucosal lesions) are present, treatment with Acebrophylline should be discontinued immediately and a doctor should be constituted. No cases of habituation, dependence, etc. have been reported. Acebro™ 10mg/ml syrup contains sucrose. Patients with rare hereditary problems of fructose intolerance, glucose-galactose malabsorption or sucrose-isomaltase insufficiency should not take these medicines. Acebro™ 10mg/ml syrup contains methyl p-hydroxybenzoate and propyl p-hydroxybenzoate which can cause allergic reactions (even delayed).

4.5. INTERACTION WITH OTHER MEDICINAL PRODUCTS AND OTHER FORM OF INTERACTIONS:

- With furosemide: enhancement of diuresis.
- Concomitant administration of reserpine may result in tachycardia.

4.6. FERTILITY, PREGNANCY AND LACTATION:

Fertility: No negative effects of Acebrophylline on foetal development have been observed.

Pregnancy: Its use should be avoided in the first months of pregnancy and in the subsequent period should be limited exclusively to cases in which the doctor considers that the lack of control of asthma constitutes a real risk for the mother.

Breast-feeding: Do not use during breast-feeding.

4.7. EFFECTS ON ABILITY TO DRIVE AND USE MACHINES:

Acebrophylline does not alter the ability to drive vehicles or use machinery.

4.8. UNDESIRABLE EFFECTS:

Acebrophylline, at adequate doses, is usually well tolerated. In analogy with what has been reported with other xanthine derivatives, in case of excessively high doses of the product, nausea, vomiting, epigastric pain, haematemesis, diarrhoea, headache, irritability, insomnia, tachycardia, extrasystole, hypotension, tachypnoea and occasionally albuminuria and hyperglycemia may occur. In case of overdose, generalized tonic-clonic convulsive seizures and serious ventricular arrhythmias may occur. These manifestations may constitute the first signs of intoxication. The appearance of side effects may require the suspension of treatment, which may be resumed, if necessary, at lower doses after the disappearance of all signs and symptoms of toxicity.

The frequency of adverse reactions is classified according to the following convention: Very Common: ≥ 1/10 (≥ 10%), Common: ≥ 1/100 and < 1/10, (≥ 1% and <10%), Uncommon: ≥ 1/1000, < 1/100, Rare: ≥ 1/10,000 and < 1/1000, Very Rare: < 1/10,000, Not Known (frequency cannot be estimated from the available data).

Immune system disorders: ***Rare:*** Hypersensitivity reactions.

Skin and subcutaneous tissue disorders: ***Rare:*** Rash, urticaria. ***Not known:*** Serious cutaneous adverse reactions (including erythema multiforme, Stevens-Johnson syndrome/toxic epidermal necrolysis, and acute generalized exanthematous pustulosis).

4.9. OVERDOSE:

No cases of overdose have been reported. However, in such an event, if there are no convulsions, it is advisable to induce vomiting by administering a cathartic and activated charcoal. In case of convulsions, provide respiratory assistance and administer oxygen, diazepam IV, rehydrate and monitor blood pressure.

5. PHARMACOLOGICAL PROPERTIES

5.1. PHARMACODYNAMIC PROPERTIES:

Pharmacotherapeutic group: Other systemic drugs for obstructive airway disorders – xanthine derivatives.

ATC code: R03DA.

Acebro™ is able to act on the various pathogenic factors that lead to bronchial obstruction.

Mechanism of action: Acebrophylline is a drug that, administered orally, is absorbed from the gastrointestinal tract, providing blood levels of 7-theophyllineacetic acid and ambroxol. This characteristic justifies its dual bronchodilator action and favorable activity on bronchial secretions. The bronchodilatory activity is expressed through the increase in the content of cyclic AMP in the tracheobronchial musculature. In addition to modifying the

rheological characteristics of mucus, ambroxol acetylcholine increases mucociliary clearance both "in vitro" and "in vivo".

5.2. PHARMACOKINETICS:

Oral administration of Acebrophylline in healthy adult subjects causes the appearance in the serum of high concentrations of active ingredient which persist in the blood for several hours. The plasma half-life is 3-5 hours after oral administration.

5.3. PRECLINICAL SAFETY DATA:

Acute toxicity tests conducted in mice and rats have demonstrated that the compound has low oral toxicity. The DL_{50} in fact it is equal to 2325mg/kg in rats and 1724mg/kg in mice. Repeated dose toxicity tests and foetal toxicity studies have also demonstrated that Acebrophylline does not cause alterations even at doses far higher than the therapeutic ones. No mutagenic action was highlighted.

6. PHARMACEUTICAL PARTICULARS

6.1. LIST OF EXCIPIENTS:

- Sucrose
- Glycerol
- Methyl p-hydroxybenzoate
- Propyl p-hydroxybenzoate
- Peppermint flavor
- Menthol flavor
- Purified water

6.2. INCOMPATIBILITIES:

Not applicable.

6.3. SHELF LIFE:

See expiry on the pack.

6.4. SPECIAL PRECAUTIONS FOR STORAGE:

Do not store over 30°C, and protect from heat, light and freezing.
Improper storage may deteriorate the medicine.
Keep out of reach of children.

6.5. NATURE AND CONTENTS OF CONTAINER:

Amber glass bottle with tamper-proof aluminium cap with P.E. wad, pack size is 60ml.

6.6. SPECIAL PRECAUTIONS FOR DISPOSAL OF A USED PRODUCT:

Any unused medicinal product or waste material should be disposed of in accordance with local requirements. Medicine should not be used if container is leaking or it contains undissolved particle(s).

6.7. DRUG PRODUCT SPECIFICATIONS:

Innovator's Specs.

7. REGISTRATION / MARKETING AUTHORISATION HOLDER

Manufactured by:
SAMI Pharmaceuticals (Pvt.) Ltd.
F-95, Off Hub River Road, S.I.T.E., Karachi-Pakistan
www.samipharma.com
Mfg Lic. No. 000072

8. REGISTRATION / MARKETING AUTHORISATION NUMBER(S)

120209

9. DATE OF FIRST AUTHORISATION / RENEWAL OF THE AUTHORISATION

16th August, 2024

10. DATE OF REVISION OF THE TEXT

اسیبرو™ سیرپ

(اسیبرو فائیلین)

ہدایات:

خوراک ڈاکٹر کی ہدایت کے مطابق استعمال کریں۔

صرف رجسٹرڈ ڈاکٹر کے نسخے کے مطابق فروخت کریں۔

بچوں کی پہنچ سے دور رکھیں۔

دوا کو ۳۰ ڈگری سینٹی گریڈ سے زیادہ درجہ حرارت پر نہ رکھیں،

گرمی، روشنی اور منجمد ہونے سے محفوظ رکھیں ورنہ دوا خراب ہو جائیگی۔

دوا کے لیک ہونے یا اس میں کوئی غیر حل پزیر شے نظر آنے کی صورت میں ہرگز استعمال نہ کریں۔