

CORDINE LS

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

Abbreviated Prescribing information for CORDINE LS (Levosalbutamol, Ambroxol Hydrochloride & Guaiphenesin Syrup) [Please refer the complete prescribing information for details].

PHARMACOLOGICAL PROPERTIES:

Mechanism of Action: *Levosalbutamol Sulphate:* is a β_2 adrenergic receptors on airway smooth muscle are Gs coupled and their activation by levosalbutamol leads to activation of adenylate cyclase and to an increase in the intracellular concentration of 3',5'-cyclic adenosine monophosphate (cyclic AMP). Increased cyclic AMP activates protein kinase A which itself inhibits the phosphorylation of myosin produces lower intracellular ionic calcium concentrations, inducing muscle relaxation. Increased cyclic AMP concentrations are also associated with the inhibition of the release of mediators from mast cells in the airways, potentially contributing to its benefit in asthma attacks. *Guaiphenesin:* Guaifenesin is thought to act as an expectorant by increasing the volume and reducing the viscosity of secretions in the trachea and bronchi. It may aid in the flow of respiratory tract secretions, allowing ciliary movement to carry the loosened secretions upward toward the pharynx. *Ambroxol Hydrochloride:* Ambroxol is a secretolytic agent used in the treatment of respiratory diseases associated with viscid or excessive mucus. The substance is a mucoactive drug with several properties including secretolytic and secretomotoric actions that restore the physiological clearance mechanisms of the respiratory tract which play an important role in the body's natural defence mechanisms. It stimulates synthesis and release of surfactant by type II pneumocytes. Surfactants acts as an anti-glue factor by reducing the adhesion of mucus to the bronchial wall, in improving its transport and in providing protection against infection and irritating agents.

INDICATIONS: It is indicated for the symptomatic relief of bronchospasm in bronchial asthma & chronic bronchitis.

DOSAGE AND ADMINISTRATION: **Dosage form:** Oral Syrup (Sugar Free), **Adults dose:** 5–10 ml thrice daily and **Paediatric Patients (aged 6–12 years) dose:** 5 mL thrice daily or as directed by the physician.

CONTRAINDICATION: Known hypersensitivity to any of the components of the formulation, Patients with pre-existing ischaemic heart disease or those patients with significant risk factors for ischaemic heart disease, Patients with gastric ulceration, It should not be used for threatened abortion during the first or second trimester of pregnancy, Levosalbutamol and beta-blocking drugs such as propranolol should not usually be prescribed together

WARNINGS & PRECAUTIONS: Cordine LS Syrup should be used with caution in patients with diabetes mellitus, serious cardiovascular disorders, hypertension, hyperthyroidism and peptic ulcers, *levosalbutamol sulphate:* caution if you have any of the co-morbidities like paradoxical bronchospasm, deterioration of asthma, cardiovascular effects, use of anti-inflammatory agents(corticosteroids), co-existing conditions (cardiovascular disorders, convulsive disorders, hyperthyroidism, or diabetes mellitus; and in patients who are unusually responsive to sympathomimetic amines.), hypokalaemia. *Guaifenesin:* be carefull if your child suffers from chronic cough, asthma or is suffering from an acute asthma attack. Stop use and consult a healthcare professional if your child's cough lasts for more than 5 days, comes back, or is accompanied by a fever, rash or persistent headache. Do not give with a cough suppressant and Caution should be exercised in the presence of severe renal or severe hepatic impairment, *Ambroxol Hydrochloride:* Care should be taken to avoid contact with the eyes and skin, and serious ingestion or inhalation. In cases of severe renal failure, an accumulation of metabolites

formed in the liver must be considered. In patients with a tendency for peptic ulcers, the use of ambroxol hydrochloride should be carefully considered. Moreover patients with malignant cilia syndrome, the advantages of secretion liquefaction should be carefully weighed against the risk of a secretory obstruction.

DRUG INTERACTIONS: *Levosalbutamol Sulphate* with Short-Acting Bronchodilators, Beta Blockers, Diuretics, Digoxin, Monoamine Oxidase Inhibitors or Tricyclic Antidepressants, Halogenated Anaesthetics. *Guaiphenesin* should not be combined with cough suppressants in the treatment of cough since the combination is illogical and patients may be exposed to unnecessary adverse effects. *Ambroxol Hydrochloride* simultaneous use with antibiotics (amoxicillin, cefuroxim, erythromycin, doxycyclin) results in an increase of concentration of the antibiotics in the lung tissue. Concomitant use with antitussive agents, e.g. codeine should be avoided, because they may inhibit cough reflex.

ADVERSE REACTIONS: *Levosalbutamol Sulphate:* Potentially serious hypokalaemia this effect may be potentiated by hypoxia. Particular caution is advised in severe asthma; in such cases, monitoring of serum potassium levels is recommended. Other side effects such as palpitation, fine tremors of the skeletal muscle (particularly the hands), and muscle cramps, gastrointestinal disturbances such as nausea, vomiting, burning substernal or epigastric pain, and diarrhoea, nervousness, headache, dizziness, fatigue and sleeplessness may occur. *Ambroxol Hydrochloride:* *Common* are dysgeusia, respiratory and gastrointestinal disorders. nausea, oral and pharyngeal hypoesthesia. *Rare effects* like rash, urticaria, hypersensitivity reactions, anaphylactic reactions, including anaphylactic shock; angio-oedema, pruritus and other hypersensitivity reactions, severe cutaneous adverse reactions (including erythema multiforme, Stevens-Johnson syndrome, toxic epidermal necrolysis and acute generalised exanthematous pustulosis)Nervous System

MARKETED BY:



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(Additional information is available on request)