SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

PRODUCT NAME

GENERIC: Ambroxol Hydrochloride, Salbutamol Sulfate, Guaifenesin and Levomenthol Syrup

BRAND NAME: MUCOLEX

DESCRIPTION:

Orange coloured clear liquid.

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 5ml contains:

Ambroxol Hydrochloride BP…….30 mg

Salbutamol Sulfate BP Equivalent to Salbutamol……..1 mg

Guaifenesin BP……50 mg

Levomenthol BP……..0.5 mg

In a Flavoured Syrupy Base…… q.s.

Colour: Sunset Yellow FCF

For complete list of excipients refer section 6.1.

3. PHARMACEUTICAL FORM:

Liquid Oral Dosage Form- Syrup

4. CLINICAL PARTICULARS

4.1 Therapeutic Indication:

Mucolex is indicated in adults, adolescents and children aged 2 to 12 years for symptomatic relief in treatment of productive cough associated with various respiratory disorders like acute bronchitis, acute exacerbation of chronic bronchitis(AECB), Pneumonia, asthamatic bronchitis etc.

4.2 Posology and method of administration:

Children 2 to 6 years= 2.5ml three times a day

- Children 6 to 12 years= 5ml two to three times a day
- Children 12 years and above and Adults= 5ml three times a day or 10ml two times a day

OR

As directed by physician.

4.3 Contraindications:

Eclampsia and severe pre-eclampsia; intra-uterine infection, intra-uterine foetal death, antepartum haemorrhage, placenta praevia and cord compression, threatened miscarriage, cardiac disease. Hypersensitivity to the active substance or any of the excipients listed herewith.

4.4 Warning and precautions for use

Pregnancy

Administration of drugs during pregnancy should only be considered if the expected benefit to the mother is greater than any possible risk to the foetus.

Breast-feeding

Avoid usage in lactating mothers.

Mild to moderate pre-eclampsia. Arrhythmias, hyperthyroidism, hypertension, DM, myocardial insufficiency, susceptibility to QT-interval prolongation. Monitor serum potassium levels. In women treated for premature labour, monitor hydration status, cardiac and respiratory function. Minimise volume of infusion fluid. Discontinue treatment if patient develops signs of pulmonary oedema.

4.5 Drug Interactions

Diuretics, corticosteroids and xanthines may augment hypokalaemia. CV effects potentiated by MAOIs, TCAs, sympathomimetics. Increases absorption of sulfamethoxazole when used together. May markedly increase heart rate and BP when used with atomoxetine. Reduces serum levels of digoxin. Hypokalaemia induced by salbutamol increases the risk of digitalis toxicity. BP should be closely monitored if linezolid is used concurrently with salbutamol.

4.6 Pregnancy & Lactation

Pregnancy

Administration of drugs during pregnancy should only be considered if the expected benefit to the mother is greater than any possible risk to the foetus.

Breast-feeding

Avoid usage in lactating mothers.

Mild to moderate pre-eclampsia. Arrhythmias, hyperthyroidism, hypertension, DM, myocardial insufficiency, susceptibility to QT-interval prolongation. Monitor serum potassium levels. In women treated

for premature labour, monitor hydration status, cardiac and respiratory function. Minimise volume of infusion fluid. Discontinue treatment if patient develops signs of pulmonary oedema.

4.7 Effects on ability to drive and use machines:

None reported.

4.8 Adverse Effects

Pregnancy; mild to moderate pre-eclampsia. Arrhythmias, hyperthyroidism, hypertension, DM, myocardial insufficiency, susceptibility to QT-interval prolongation. Monitor serum potassium levels. In women treated for premature labour, monitor hydration status, cardiac and respiratory function. Minimise volume of infusion fluid. Discontinue treatment if patient develops signs of pulmonary oedema.

4.9 Overdose

May lead to tachycardia, tremor, CNS stimulation, hypokalaemia and hyperglycaemia. Symptomatic treatment is recommended.

5. PHARMACOLOGICAL PROPERTIES:

Ambroxol Hydrochloride: Ambroxol is a clinically proven systemically active mucolytic agent.

When administered orally onset of action occurs after about 30 minutes. The breakdown of acid mucopolysaccharide fibers makes the sputum thinner and less viscous and therefore more easily removed by coughing. Although sputum volume eventually decreases, its viscosity remains low for as long as treatment is maintained.

Guaifenesin: Guaifenesin is an expectorant which increases the output of phlegm (sputum) and bronchial secretions by reducing adhesiveness and surface tension. The increased flow of less viscous secretions promotes ciliary action and changes a dry, unproductive cough to one that is more productive and less frequent. By reducing the viscosity and adhesiveness of secretions, guaifenesin increases the efficacy of the mucociliary mechanism in removing accumulated secretions from the upper and lower airway.

Salbutamol Sulphate: Salbutamol, a moderately selective beta(2)-receptor agonist similar in structure to terbutaline, is widely used as a bronchodilator to manage asthma and other chronic obstructive airway diseases. The R-isomer, levalbuterol, is responsible for bronchodilation while the S-isomer increases bronchial reactivity. The R-enantiomer is sold in its pure form as Levalbuterol. The manufacturer of levalbuterol, Sepracor, has implied (although not directly claimed) that the presence of only the R-enantiomer produces fewer side-effects.

5.2 Pharmacokinetic properties

Ambroxol hydrochloride: When administered orally onset of action occurs after about 30 minutes. The breakdown of acid mucopolysaccharide fibers makes the sputum thinner and less viscous and therefore more easily removed by coughing.

Salbutamol Sulphate: Salbutamol is a beta (2)-adrenergic agonist and thus it stimulates beta(2)-adrenergic receptors. Binding of albuterol to beta (2)-receptors in the lungs results in relaxation of bronchial smooth muscles. It is believed that salbutamol increases cAMP production by activating adenylate cyclase, and the actions of salbutamol are mediated by cAMP. Increased intracellular cyclic AMP increases the activity of cAMP-dependent protein kinase A, which inhibits the phosphorylation of myosin and lowers intracellular calcium concentrations. A lowered intracellular calcium concentration leads to a smooth muscle relaxation and bronchodilation. In addition to bronchodilation, salbutamol inhibits the release of bronchoconstricting agents from mast cells, inhibits microvascular leakage, and enhances mucociliary clearance.

Guaifenesin: Guaifenesin may act as an irritant to gastric vagal receptors, and recruit efferent parasympathetic reflexes that cause glandular exocytosis of a less viscous mucus mixture.

Cough may be provoked. This combination may flush tenacious, congealed mucopurulent material from obstructed small airways and lead to a temporary improvement in dyspnea or the work of breathing.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Citric acid monohydrate, Disodium Edetate, Sodium Benzoate, Potassium Sorbate, Sugar S-30, Propylene Glycol, Glycerol, Sorbitol 70% (Non-crystallizing), Colour Sunset Yellow FCF Supra, Flavour Raspberry ASV, Flavour Sweet Orange RSWL

6.2 Incompatibilities

Not Applicable

6.3 Shelf Life

24 Months

6.4 Special precautions for storage:

Do not store above 30°C. Protect from light.
Keep the medicine out of reach of children.

6.5 Nature and contents of container

100 ml amber coloured glass bottle

6.6 Special precautions for disposal and other handling

Any unused product or waste material should be disposed of in accordance with local requirements

7. APPLICANT

Manufactured by:

S Kant HEALTHCARE Ltd.

1802-1805, G.I.D.C., Phase III,

Vapi - 396 195. Gujarat, INDIA.

8. WHO PREQUALIFICATION REFERENCE NUMBER

Not applicable

9. DATE OF PREQUALIFICATION / RENEWAL OF PREQUALIFICATION

Not applicable

10. DATE OF REVISION OF THE TEXT

Not applicable