Summary of Product Characteristics for Pharmaceutical Products

1. Name of the medicinal product:
Respimax® syrup

2. Qualitative and quantitative composition
Each 5ml contains Ambroxol Hydrochloride BP 15 mg / Salbutamol Sulfate BP 1 mg / Guaifenesin BP 50 mg

3. Pharmaceutical form
Reddish pink to pink coloured, viscous liquid containing flavoured syrupy base.

4. Clinical particulars

4.1 Therapeutic indications
Respimax is indicated in productive cough associated with asthmatic bronchitis, bronchospasm, chronic obstructive pulmonary disease (COPD), Smokers cough.

Ambroxol Hydrochloride
Ambroxol Hydrochloride indicated in Acute and chronic diseases of respiratory tracts associated with viscid mucus including acute and chronic bronchitis, Productive cough, Inflammatory diseases of Rhinopharyngeal tract (e.g. Laryngitis, Pharyngitis, Sinusitis and Rhinitis) associated with viscid mucus, Asthmatic bronchitis, Bronchial asthma with difficult departure of mucus, Bronchiectasis, Chronic pneumonia.

Salbutamol Sulfate
Salbutamol is indicated in adults, adolescents and children aged 4 to 11 years. Salbutamol is a selective B2-agonist providing short-acting (4-6 hour) bronchodilation with a fast onset (within 5 minutes) in reversible airways bronchospasm unresponsive to conventional therapy, and in the treatment of acute severe asthma.

Guaifenesin
Symptomatic relief of deep chesty coughs and to soothe the throat.

4.2 Posology and method of administration

Posology
2-6 years: 2.5 ml (1/2 teaspoonful) 2-3 times a day
5-10 years: 5 ml (1 teaspoonful) 2-3 times a day
10 years and adults: 10 ml (2 teaspoonful) 3 times a day.

Method of administration
For oral use.

4.3 Contraindications
Contraindicated in known hypersensitivity to Ambroxol or Bromhexine. Hypersensitivity to Salbutamol and guaifenesin or any of excipients used in formulation.
Ambroxol is also contraindicated in patients with completely impaired renal function and with gastric ulceration.
Salbutamol is also contraindicated in patients with pre-existing cardiac tachyarrhythmias.

4.4 Special warnings and precautions for use

Ambroxol Hydrochloride
Ambroxol should be given cautiously to patients with gastric and duodenal

ulceration or convulsive disorders. Patients with hepatic and renal insufficiency should take it with caution.

Salbutamol Sulfate

In case of severe asthma, Patient requires regular medical assessment with medication of bronchodilators. The dosage can be increased after medical advice. Short-acting inhaled bronchodilators can be taken with this syrup. Salbutamol should be administered cautiously to patients suffering from thyrotoxicosis.

Should be used with caution in patients with cardiac arrhythmia, hypertension, convulsive disorders and diabetes mellitus. It should be taken with extreme caution in persons taking tricyclic antidepressants, monoamine oxidase inhibitors, loop diuretics or thiazide diuretics. Beta-receptor blocking drugs should be avoided during salbutamol therapy because these drugs block the bronchodilator effect of salbutamol

Guaifenesin

Do not take if you are allergic to guaifenesin.

Should not use in excessive amount because may cause nausea and vomiting. If cough persists for more than one week, accompanied by high fever, rash or headache, consult the physician.

4.5 Interaction with other medicinal products and other forms of interaction

Ambroxol hydrochloride:

Drug interactions for ambroxol hydrochloride are not known.

Salbutamol:

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.

Guaifenesin:

No medications are expected to react with guaifenesin when taken alone. However, this does not mean that drug interactions can be dismissed when taking guaifenesin. Because it is often combined with other medicines in cold and cough products, those other medicines could cause drug interactions. Check the ingredient list, and consult your healthcare provider before taking guaifenesin with any medications.

4.6 Pregnancy and Lactation

Ambroxol hydrochloride

Has not been shown to have any teratogenic or toxic effects on the foetus. It is advisable to avoid use during the first trimester of pregnancy.

Salbutamol

Is a pregnancy category C drug. It should be used during pregnancy only if absolutely essential. During pregnancy, inhalation of salbutamol has particular advantage as the therapeutic action can be achieved without the requirement for such plasma concentration liable to have an effect on the fetus.

Guaifenesin

Available evidence and/or expert consensus is inconclusive or is inadequate for determining infant risk when used during pregnancy and breastfeeding. Weigh the potential benefits of drug treatment against potential risks before taking this drug during pregnancy and breastfeeding.

4.7 Effects on ability to drive and use machines

Guaifenesin

Use caution when driving, operating machinery, or performing other hazardous activities. Guaifenesin may cause dizziness. If you experience dizziness, avoid these activities.

4.8 Undesirable effects

Adverse reactions

Most common adverse reactions may include tachycardia, arrhythmia, flushing, myocardial ischemia, disturbances of sleep and behaviour. Ambroxol include gastrointestinal side effects may occur but these are mild. Salbutamol include fine tremor, anxiety, headache, muscle cramp, dry mouth and palpitation.

Reporting of suspected 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. Healthcare professionals are asked to report any suspected adverse reactions via Pharmacy and Poisons Board-Pharmacovigilance Electronic Reporting System (PvERS); *https://pv.pharmacyboardkenya.org* .

4.9 Overdose

Ambroxol hydrochloride:

No information is available on overdosage with ambroxol hydrochloride.

Salbutamol:

The most common symptoms of overdose with salbutamol are tremor, palpitation and tachycardia. It may also produce arrhythmias, hypertension, angina, seizures, nervousness, fatigue, malaise, headache, dizziness, sleeplessness, dry mouth and even cardiac arrest. Treatment is symptomatic with discontinuation of salbutamol is needed. A cardioselective beta receptor blocking drug may be given by intravenous injection in patients presenting with tachycardia and palpitation. In general, beta receptor blocking drugs should be used cautiously as they may cause bronchospasm in sensitive persons. Hypokalaemia may occur following overdose with salbutamol. Serum potassium level should be monitored.

Guaifenesin:

Nausea and vomiting may occur. In the event of overdosage, discontinue medication and seek medical help immediate.

5. Pharmacological properties

5.1 Pharmacodynamic properties

Ambroxol Hydrochloride

Pharmacotherapeutic group: Mucolytics,
ATC code: R05CB06

It plays an important role in the body's defence mechanisms and resulting in more productive cough. The pharmacological effect is exerted on mucus quality, ciliary f unction and the production of alveolar surfactant. It clears granules of mucus that have already formed, normalizes secretion viscosity

and finally regularizes the activity of the tubuloacinar glands in the respiratory tract. It increases the speed of transport of secretion produced and finally normalizes respiratory tone, improving expectoration.

Salbutamol Sulfate

Pharmacotherapeutic group: Andrenergics, inhalants. Selective beta-2-andrenoreceptor agonists,

ATC code: R03AC02

Salbutamol is a selective β2-agonist providing short-acting (4-6 hour) bronchodilation with a fast onset (within 5 minutes) in reversible airways obstruction. At therapeutic doses it acts on the β2-adrenoceptors of bronchial muscle. With its fast onset of action, it is particularly suitable for the management and prevention of attack in asthma.

Guaifenesin

Pharmacotherapeutic group: Expectorants,

ATC Code: R05CA03

Guaifenesin is reported to reduce the viscosity of tenacious sputum and is used as an expectorant. The active ingredient is not known to cause sedation.

5.2 Pharmacokinetic properties

Ambroxol hydrochloride:

Absorption:

Ambroxol hydrochloride is rapidly absorbed (70-80%) after oral administration. The time to reach peak plasma concentration is approximately 2 hours.

Distribution:

The distribution half-life of ambroxol hydrochloride is around 1.3 hours.

It is extensively bound to plasma proteins (90%).

Metabolism:

Metabolite is dibromoanthranilic acid (activity unspecified).

Excretion:

Primarily via the kidneys. Renal clearance (rate) is approximately 53 ml/minute; approximately 5-6% of a dose is excreted unchanged in the urine. The elimination half-life of ambroxol hydrochloride is biphasic, with an alpha half-life of 1.3 hours and a beta half-life of 8.8 hours.

Salbutamol:

After oral administration, approximately 50% of salbutamol is absorbed from the intestinal tract with a slower onset of action, reaching a peak at about 2 hours after intake. After inhalation, salbutamol reaches the lungs directly and acts within 3-5 minutes with a peak at 15-20 minutes. Overall duration of action of salbutamol is 4-6 hours. It is metabolized in the intestinal tract and in the liver and is excreted via the urine.

Guaifenesin:

Guaifenesin is well absorbed from the gastrointestinal tract. It is metabolised and then excreted in the urine. The half-life in plasma is approximately 1 hour.

5.3 Preclinical safety data

Non-clinical data revealed no special hazard for humans based on conventional studies of safety pharmacology, repeated dose toxicity, genotoxicity, carcinogenic potential, and toxicity to reproduction.

6. Pharmaceutical Particulars

6.1 List of Excipients

Excipients	Specification	Quantity (mg)/ ml
Menthol	USP	1.000
Sorbitol solution (70%)	BP	2500.000
Sodium methyl hydroxybenzoate	BP	5.000
Sodium propyl hydroxybenzoate	BP	0.500
Di Sodium EDETATE	BP	1.000
Bronopol	BP	1.000
Citric acid (anhydrous)	BP	5.000
Saccharin Sodium	BP	2.500
Propyline Glycol	BP	333.333
Xantham gum FNCS	BP	10.000
Ponceau 4 R	IH	0.100
Raspberry	IH	0.0033ml
Peppermint	IH	0.0017ml
Purified water	BP	q.s.

6.2 Incompatibilities

None.

6.3 Shelf-Life

24 months

6.4 Special Precautions for storage

Store in a cool, dry place below 30°C.

6.5 Nature and Content of container

100 ml Amber PET bottle packed in a carton along with a leaflet.

6.6 Special precautions for disposal and other handling

7. Marketing Authorization Holder

BEKRAPHARMA UKLTD. 13/091,
Lavington Road, Beddington,
London. United Kingdom

8. Marketing Authorization Number

CTD10160

9. Date of first authorization/renewal of the authorization

01/12/2023

10. Date of revision of the text

10th May, 2025