1.3 PRODUCT INFORMATION

1.3.1 Summary of Product characteristics (SmPC)

1- Name of the Medicinal Product:

1.1 Name of the Medicinal Product

- **Brand Name/ Generic Name:**RESPIMAX (Ambroxol Hydrochloride, Salbutamol Sulfate and Guaifenesin Syrup)
- **International Non-Proprietary Name (INN):**Ambroxol Hydrochloride, Salbutamol Sulfate and Guaifenesin Syrup

1.2 Strength: Ambroxol Hydrochloride 15 mg, Salbutamol Sulfte 1 mg and Guaifenesin 50mg Syrup

1.3 Pharmaceutical Form: Syrup

2- Qualitative and Quantitative Composition

Each 5 ml contains:

Ambroxol hydrochloride BP	15 mg
Salbutamol sulfate BP	
Eq. to salbutamol	1 mg
Guaifenesin BP	50mg
Mentholated syrup base	Q. S
Colour: Ponceau 4 R	

3- Pharmaceutical Form:

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

4- Clinical Particulars

4.1 Therapeutic indications

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

obstruction. Salbutamol are indicated for use in the routine management of chronic 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 pr any of excipients used in formulation.

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.

Guaifenesin

Do not take if you are allergic to guaifenesin.

4.5 Interaction with others medicinal products and other forms of Interactions Ambroxol Hydrochloride

Combination of ambroxol oral solution with cough suppressants can, due to suppressed cough reflex, cause serious obstruction of the airways.
Administration of ambroxol with antibiotics (amoxicillin, cefuroxim, and erythromycin) leads to increase of antibiotics concentrations in mucus.
No clinically relevant unfavourable interactions with other medications have been reported.

Salbutamol Sulfate

Salbutamol and non-selective beta-blocking drugs, such as propranolol, should not usually be prescribed together.

Guaifenesin
If urine is collected within 24 hours of a dose of the medicinal product, a metabolite of guaifenesin may cause a colour interference with laboratory determinations of urinary 5-hydroxyindoleacetic acid (5-HIAA) and vanillylmandelic acid (VMA). Guaifenesin may increase the rate of absorption of paracetamol.

4.6 Pregnancy and Lactation Pregnancy

No evidence of harmful effects found on the foetus during pregnancy.

Guaifenesin has been linked with an increased risk of neural tube defects in a small number of women with febrile illness in the first trimester of pregnancy. The product should be used in pregnancy only if the benefits outweigh this risk. Breast-feeding salbutamol & Ambroxol is probably secreted in breast milk its use in nursing mothers requires careful consideration.

4. 7 Effects on ability to drive and use machines None.

4.8 Undesirable Effects Ambroxol Hydrochloride

Gastrointestinal side-effects like epigastric pain, gastric fullness may occur occasionally. Rarely allergic responses such as eruption, urticaria or angioneurotic edema may occur.

ADMINISTRATIVE INFORMATION

Product Name: **RESPIMAX** (Ambroxol Hydrochloride, Salbutamol Sulfate and Guaifenesin Syrup)

Salbutamol Sulfate

Common side effects: Tremor, headache, Tachycardia. Guaifenesin

Dizziness, Drowsiness, Decreased uric acid levels, Stomach pain, Nausea, Vomiting

Headache, Rash

5. Pharmacological properties

5.1 Pharmacodynamics

Ambroxol Hydrochloride

Pharmacotherapeutic group: Mucolytics, A TC 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 function 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 2-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 2-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 Pharmacokinetics

Ambroxol Hydrochloride

Ambroxol is almost completely absorbed after oral administration. Tmax is 1-3 hours. It is extensively bound to plasma proteins (90%). Half-time of ambroxol in plasma is 7-

12 hours. Its metabolites in plasma is about 22 hours. It could cross the amniotic fluid and placenta, secreted in breast milk, and metabolized in the liver. It metabolizes under first pass metabolism. About 90% of ambroxol and its metabolites are eliminated through the kidneys. Less than 10% of ambroxol is eliminated unchanged by the kidneys. In patients with severe hepatic impairment clearance of ambroxol lowers 20 40% and accumulation of ambroxol metabolites is to be expected.

Salbutamol Sulfate

Salbutamol is readily absorbed from the gastro-intestinal tract and is subject to first pass metabolism in the liver. Peak plasma concentrations occur within one to four hours after oral administration. About half is excreted in the urine as an inactive sulphate conjugate following oral administration. The bioavailability of orally administered salbutamol is about 50%

Guaifenesin

Guaiphenesin is absorbed from the gastrointestinal tract. It is metabolised and excreted in the urine

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

Menthol USP
Sorbitol solution (70%) BP
Sodium methyl hydroxybenzoate BP
Sodium propyl hydroxybenzoate BP
Di Sodium EDETATE BP
Bronopol BP
Citirc acid (anhydrous) BP
Saccharin Sodium BP
Propyline Glycol BP
Xantham gum FNCS BP
Ponceau 4R IHS
Raspberry IHS
Peppermint IHS
Purified water BP

6.2 Incompatibilities

None.

6.3 Shelf life

24 Months

6.4 Special precautions for storage

Product Name: **RESPIMAX** (Ambroxol Hydrochloride, Salbutamol Sulfate and Guaifenesin Syrup)

Store in cool dry place below 30˚C, Protect from light.

6.5 Nature and contents of container

100ml amberP ET bottle packed in a carton along with a leaflet

7. **Marketing Authorisation holder**

BEKRAPHARMA UKLTD.
13/091, Lavington Road,
Beddington,
LONDON.
UNITED KINGDOM

8. **Marketing Authorization Number**

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9. **Date of first authorization/renewal of the authorization**

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10. **Date of revision of the text** January 15th, 2019