1. Name of the medicinal product

JEKOF SYRUP (Ambroxol HCL & Salbutamol Sulphate Syrup)

2. Qualitative and Quantitative

Composition Label Claim:

Each 5 ml Contains:

Ambroxol HCL..... 15mg

Salbutamol Sulphate

Eq. to Salbutamol .....1 mg

Color: Brillient blue & tartrazine

Excipients of known effect; Propylene Glycol (31.0/5ml) and Aspartame (1.80/5ml)

For full list of excipients, refer to. Section 6;

3. Pharmaceutical form

Liquid Syrup

Description: Green Coloured Flavoured syrup.

4. Clinical Particulars

4.1 Therapeutic indications

JEKOF SYRUP 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 Special warnings 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 Interaction with other medicinal products and other forms of interaction

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 Fertility, pregnancy and 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 Undesirable 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.

Reporting of suspected Adverse Reactions: Healthcare professionals are requested to report any suspected adverse drug reactions via the National Regulatory Authority (PPB).

4.9 Overdose

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

5. Pharmacological properties

5.1 Pharmacodynamic properties

Pharmacotherapeutic group:

Mucolytics **ATC code:** R05CB06

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.

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 Renantiomer 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.

5.3 Preclinical safety data

Not Applicable

6. Pharmaceutical particulars

6.1 List of excipients Sorbitol
Solution 70% BP
Liquid glucose BP
Sodium Benzoate BP
Citric Acid BP
Propylene Glycol (PG) USP
Aspartame BP
Sodium Citrate BP
Di Sodium E.D.T.A. BP
Colour Brilient Blue Supra
SPECI. Colour tartrazine Supra
SPECI. Menthol BP
ESS. Khus Flavour SPECI.

6.2 Incompatibilities
Not applicable.

6.3 Shelf life
24 months.

6.4 Special precautions for storage
Store in a cool & dry place. Protect from light.

6.5 Nature and contents of container
100 ml

7. Marketing Authorisation Holder and Manufacturer Marketing Authorisation Holder:
NATIONAL PHARMACY LTD,
Colchester Park,

P.O Box 17843 - 00500

Nairobi, Kenya.

Manufacturer:

BRUSSELS LABORATORIES PVT. LTD.

33. Changodar Ind. Estate. Sarkhej-Bavla Road,

Changodar, Ahmedabad-382210.

8. Marketing Authorization Number:

H2016/CTD2056/169

9. Date of first Authorization /renewal of the authorization:
renewal of the authorization: June 2026

10. Date of revision of text:

September 2024

11. DOSIMETRY (IF APPLICABLE)

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12. INSTRUCTIONS FOR PREPARATION OF

RADIOPHARMACEUTICALS (IF APPLICABLE):

N/A