

GENERIC HEALTHCARE PVT. LTD.
PECTOGEN[®] Syrup
(Salbutamol Sulphate, Bromhexine Hydrochloride, Guaifenesin Syrup)

SUMMARY OF PRODUCT CHARACTERISTICS

1.1 (Invented) name of the medicinal product

PECTOGEN[®]

1.2 Strength (per 5 ml)

Salbutamol 1 mg, Bromhexine hydrochloride 2 mg , Guaifenesin 50 mg

2. Qualitative and quantitative composition

Each 5 ml contains:

Salbutamol sulphate BP equivalent to salbutamol 1 mg

Bromhexine hydrochloride BP 2 mg

Guaifenesin BP 50 mg

Menthol BP1 mg

In a syrup base

3. Pharmaceutical form

Oral Syrup

4. Clinical particulars

4.1 Therapeutic indications

PECTOGEN syrup is indicated for symptomatic management of all productive coughs including asthmatic coughs.

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4.2 Posology and method of administration

Children: (2-6 years.) - 1 teaspoonful or.

Children: (Above 6 years.) 1-2 teaspoonful or as directed by the physician.

Adults: 2 teaspoonful or as directed by the physician.

4.3 Contraindications

PECTOGEN syrup is contraindicated for use in patients with known hypersensitivity.

4.4 Special warnings and precautions for use

PECTOGEN is to be advocated with caution in cardiovascular disorders like ischemic heart disease, hypertension and cardiac arrhythmias; hyperthyroidism, diabetes, those who are unusually responsive to sympathomimetics or who have convulsive disorders. **PECTOGEN** should be advocated during pregnancy and lactation only if strictly required. Bromhexine (in **PECTOGEN**) is required to be advocated with caution in those with peptic ulceration, severe hepatic and renal dysfunction. Menthol containing products (**PECTOGEN**) should be avoided in those with hiatal hernia, gallstones and in near-term pregnant females. Cardiac disease, diabetes, hyperthyroidism, gastric ulcer, pregnancy, lactation, hypertension, hepatic or renal impairment, arrhythmia

4.5 Interaction with other medicinal products and other forms of interaction

Salbutamol can cause deleterious cardiovascular side effects when combined with sympathomimetics. Beta blockers cannot be used together since they block salbutamol's action. Salbutamol can increase the action of monoamine oxidase inhibitors (MAOIs), nonpotassium-sparing diuretics, and digoxin tricyclic antidepressants to cause untoward reactions.

4.6 Pregnancy and lactation

Caution when used during pregnancy.

Category C: Either studies in animals have revealed adverse effects on the foetus (teratogenic or embryocidal or other) and there are no controlled studies in women or studies in women and animals are not available. Drugs should be given only if the potential benefit justifies the potential risk to the foetus.

4.7 Effects on ability to drive and use machines

Not established

4.8 Undesirable effects

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4.9 Overdose

In case of any overdose dizziness, sweating, nausea and vomiting may occur. Besides symptomatic therapy and supportive measures, gastric lavage and charcoal administration is required .

5. Pharmacological properties

5.1 Pharmacodynamic properties

Salbutamol Sulphate

Pharmacotherapeutic group: Selective beta-2-adrenoreceptor agonists

ATC Code: R03CC02

Bromhexine Hydrochloride

Pharmacotherapeutic group: Mucolytics

ATC code: R05CB02

Guaifenesin

Pharmacotherapeutic group: Expectorants

ATC Code: R05CA03

Salbutamol is a relatively selective beta2-adrenergic bronchodilator. The primary action of beta-adrenergic drugs, including salbutamol, is to stimulate adenyl cyclase, the enzyme which catalyzes the formation of cyclic-3,5-adenosine monophosphate (cyclic AMP) from adenosine triphosphate (ATP) in beta-adrenergic cells. The cyclic AMP thus formed mediates the cellular responses. Increased cyclic AMP levels are associated with relaxation of bronchial smooth muscle and inhibition of release of mediators of immediate hypersensitivity from cells, especially from mast cells.

Bromhexine is a mucolytic, and reduces the phlegm stickiness. Bromhexine acts on the mucus-producing cells of the respiratory tract and depolymerises the high molecular-weight mucopolysaccharide-protein fibers responsible for viscosity of bronchial secretions. Following thinning of bronchial mucus, bromhexine reduces airways resistance and this clears the respiratory passages by facilitating expectoration. In a variety of diseases bromhexine can improve ventilatory capacity and hence it is an extremely useful agent for optimal management of especially bronchospastic bronchopulmonary diseases.

Guaiphenesin is a conventional expectorant. Although its exact mechanism is not established, guaiphenesin is believed to act by stimulating receptors in the gastric mucosa that initiates a reflex secretion of respiratory tract fluid. This action increases the volume

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and, at the same time, decreases the viscosity of bronchial secretions. This is the basis of guaifenesin's expectorant action.

Menthol has significant clearing action on congestion of respiratory passages, especially those of the upper tract.

5.2 Pharmacokinetic properties

Salbutamol is a direct-acting sympathomimetic with β -adrenergic activity and selective action on β_2 receptors, producing bronchodilating effects. It also decreases uterine contractility.

Onset Inhalation: 5-15 min; Oral: 30 min.

Duration Inhalation: 3-6 hrs; Oral: 8 hr; .

Absorption Readily absorbed from the GI tract.

Metabolism Hepatic and in the gut wall.

Excretion Via the urine as metabolites and unchanged drug. Some excretion in the faeces.

5.3 Preclinical safety data

Not established

6. Pharmaceutical particulars

6.1 List of excipients

Sucrose, Propylene Glycol, Sorbitol (70 %), Glycerine, Sodium Benzoate, Citric acid, Colour Sunset Yellow Supra, Flavour Pineapple F-1141, Flavour Black Current, Flavour Raspberry F-1236, Purified water.

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

36 months.

6.4 Special precautions for storage

Store in dry place, well-ventilated place at a temperature not exceeding 25° C. Protect from light & moisture.

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6.5 Nature and contents of container

120 ml syrup in a amber coloured PET bottle fitted with measuring cup.
Such one bottle in a printed carton alongwith leaflet.

6.6 Special precautions for disposal and other handling

Used samples should be disposed as per local requirement.

7 Registrant

GENERIC HEALTH CARE PRIVATE LIMITED
City Square, 29/A, Office No.205, Shivajinagar,
Pune-411 005, India.

8. Manufacturer

GENERIC HEALTH CARE PRIVATE LIMITED
Plot No.-81, STICE, Musalgaon,
Sinnar, Nasik, India.

9. Date of revision of the text

Not applicable

10. DOSIMETRY (IF APPLICABLE)

Not applicable

11 INSTRUCTIONS FOR PREPARATION OF RADIOPHARMACEUTICALS (IF APPLICABLE)

Not applicable