SALCOF SYRUP: SUMMARY OF PRODUCT CHARACTERISTICS

1. Name of the medicinal product

Salcof Syrup

2. Qualitative and quantitative composition

Salbutamol 1mg/5ml

Bromhexine HCl 12mg/5ml

Guaiphenesin 50mg/5ml

For the full list of excipients, see section 6.1.

3. Pharmaceutical form

Syrup

A Clear orange liquid.

4. Clinical particulars

4.1 Therapeutic indications

Salbutamol: Beta2-Adrenergic Agonist, Phenethylamine derivative, Bronchodilator

(Antiasthma), uterine relaxant.

Guaiphenesin: Propanediol derivative, expectorant.

Bromhexine: As expectorant and mucolytic, conditions associated with production of viscid mucous, bronchitis, pharyngitis, laryngitis, rhinitis, sinusitis, asthmatic bronchitis, mucous bronchiectasis and chronic pneumonia.

4.2 Posology and method of administration

Salbutamol

Adult:

Oral:

Immediate release tablet: 2 - 4 mg every 6 - 8 hours daily, maximum dose 32mg / day Sustained release tablets: 8 mg / day in 2 divided doses and if sufficient response does not

obtained then dose can be gradually increased to 16mg / day in 2 divided doses

Children: 6 - 14 years

Syrup: 6 - 8mg / day in 3 - 4 divided doses and if needed dose can be increased maximum up to 24mg / day

Uterine Relaxant: (I.V) 4 to 32 mcg/minutes

Guaiphenesin

Oral :

Adults and children over 12 years: 100 to 400mg up to 6 times daily as required.Maximum dose: 2.4g/day

Children (age 6 to 11): 100 to 200mg up to 6 times daily as required.Maximum dose:

1.2g/day

Children (age 2 to 5): 50 to 100mg up to 6 times daily as required.Maximum dose:

600mg/day

Extended release:

Adults and children over 12 years: 600 to 1200mg twice daily. Not to exceed 2.4g in 24 hours

Children (age 6 to 12): 600mg twice daily. Not to exceed 1.2g in 24 hours

Children (age 2 to 6): 300mg twice daily. Not to exceed 600mg in 24 hours

Thick or sticky cervical mucus: 200mg 2 to 3 times daily from 4 days prior to ovulation and continue through ovulation day.

Bromhexine

Oral: 8mg thrice daily. Children (5 to 10 years): 4mg thrice daily Children (1 to 5 years): 4mg twice daily.

4.3 Contraindications

Salbutamol

Hypersensitivity to Salbutamol and other sympathomimetic amines

Guaiphenesin

- 1. Hypersensitivity to the drug
- 2. Chronic or persistent cough associated with chronic lower respiratory tract diseases
- 3. Asthma
- 4. Bronchitis
- 5. Chronic obstructive pulmonary disease (COPD)
- 6. Emphysema

Bromhexine

Hypersensitivity to the drug

4.4 Special warnings and precautions for use

Salbutamol

- a) Myocardial insufficiency
- b) Arrhythmia
- c) Hypertension
- d) Hyperthyroidism
- e) Epilepsy
- f) Diabetes

Guaiphenesin

a) Porphyria

Bromhexine

- a) Hepatic impairment
- b) Renal impairment
- c) Gastric and duodenal ulcer
- d) Convulsive disoders

4.5 Interaction with other medicinal products and other forms of interaction

Salbutamol

Beclomethasone, Theophylline: Enhances respiratory function.

Beta-blockers: Inhibit bronchodilator effect.

Diuretics and Xanthines: Increased risk of hypokalemia.

Digitalis: Increased risk of digitalis toxicity when salbutamol is given in hilgh doses due to hypokalaemia.

4.6 Fertility, pregnancy and lactation

Pregnancy

Salbutamol

Use with caution

Guaiphenesin

Use with caution

Bromhexine

Contraindicated

Breast-feeding

Salbutamol.

Use with caution

Guaiphenesin

Contraindicated

Bromhexine

Contraindicated

4.7 Effects on ability to drive and use machines

Causes dizziness and drowsiness. Do not drive or use machines while under Salcof syrup medication.

4.8 Undesirable effects

Salbutamol

Drowsiness, Headache, dizziness, nervousness, tremor, weakness, palpitations, tachycardia, arrythmia, vomiting, nausea, heartburn, diaphoresis and hypokalemia (high dose).

Guaiphenesin

Headache, dizziness, nausea, vomiting, rash, diarrhoea, drowsiness and stomach pain.

Bromhexine

Rhinorrhea, lacrimations, allergic reactions and gastric irritation

4.9 Overdose

Salbutamol

Give supportive measures and symptomatic treatment. Drug can be removed from the body by gastric lavage or by inducing emesis. Absorption of drug can be reduced by administration of activated charcoal

Bromhexine

Provide symptomatic treatment and supportive measures

5. Pharmacological properties

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Mucolytic

Mechanism of action

Salbutamol

Salbutamol is a short acting $\beta 2$ receptor agonist. It selectively stimulates $\beta 2$ receptors present in airway, Uterus, and Vascular Smooth muscles. It directly relaxes the airway smooth muscles and produces bronchodilation. Stimulation of $\beta 2$ receptors activates Gs adenylylcyclase -cyclic AMP path way and produces reduction in smooth muscle tone. $\beta 2$ receptor agonists also increases the conductance of large Ca2+sensitive K+ channels in airway smooth muscles and leads to membrane hyperpolarisation and relaxation of smooth muscles. $\beta 2$ receptor agonists also suppress the release of Leukotrienes and histamine from the mast cells in the lung tissue and enhance mucociliary function and decrease micro vascular permeability and also inhibits Phospholipase A2 which produces inhibition of prostaglandins production. Thus, Salbutamol can inhibit the broncho-constriction produced by inflammatory mediators. Salbutamol is effective in the management of preterm labour.

Guaiphenesin

Guaiphenesin is an expectorant which after absorption from the gastrointestinal tract secreted by tracheobronchial glands and directly increase bronchial secretion and mucosal ciliary action. It increases respiratory tract fluid by reducing adhesiveness and surface tension, reducing viscosity of the secretions and there by facilitating their removal and clears chest congestion.

Action in local vaginal preparations: Guaiphenesin helps to thin the thick or sticky cervical mucus

Bromhexine

Bromhexine hydrochloride acts as a mucokinetic and mucolytic agent. It decreases mucus viscosity by altering its structure. It depolymerises mucopolysaccharides directly as well as by liberating lysosomal enzymes and network of fibres in tenacious sputum is broken. It induces thin copious bronchial secretion.

5.2 Pharmacokinetic properties

Salbutamol

Absorption:

It is well absorbed after oral administration.

Distribution:

Salbutamol does not cross the blood brain barrier

Metabolism: It is metabolized to inactive metabolites in the live.

Excretion:

Salbutamol is excreted primarily in the urine and small amounts un faeces.

Onset of action: 15 - 30 minutes

Duration of action: 6 - 12 hours

Half-life: 4 hours

Guaiphenesin

Absorption: Well absorbed orally.Distribution: It is secreted by the tracheobronchial glands. Metabolism: It is metabolized primarily to Beta-2-methoxyphenoxy-lactic acid. Excretion: It is excreted in the urine.

Half life: 60 minutes

Bromhexine

Absorption: Bromhexine hydrochloride is rapidly absorbed from the gastrointestinal tract and bioavailability is about 20%.

Distribution: It is widely distributed to body tissues in a highly protein bound form; Bromhexine crosses the blood brain barrier and small amounts cross the placenta, Metabolism: It undergoes extensive first-pass metabolism in the liver. Excretion: It is excreted primarily in the urine mainly as metabolites

5.3 Preclinical safety data

Not Available

6. Pharmaceutical particulars

6.1 List of excipients

- Sodium CMC (High Visc)
- Menthol crystals
- Propylene glycol
- Glycerine
- Sodium benzoate
- Sodium saccharin
- Sorbital Solution 70%
- Colour sunset yellow
- Flavour strawberry
- Citric acid

6.2 Incompatibilities

None known

6.3 Shelf life

36 months

6.4 Special precautions for storage

Store below 30°C.

6.5 Nature and contents of container

60ml, 100ml and 180ml in amber colored bottles packed in unit boxes with patient information leaflets enclosed

6.6 Special precautions for disposal and other handling

Not applicable.

7. Marketing authorisation holder

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