
Bromhexine Hydrochloride, Dextromethorphan, Ammonium Chloride & Menthol Syrup

Summary of Product Characteristics

Document type: Summary of Product Characteristics
Document status: Final
Release date: 20th Feb. 2022
Number of pages: 4 pages

1 NAME OF THE MEDICINAL PRODUCT

Bromhexine Hydrochloride, Dextromethorphan, Ammonium Chloride & Menthol Syrup

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 5 ml contains:

Bromhexane Hydrochloride BP.....	4 mg
Dextromethorphan Hydrobromide BP	5 mg
Ammonium Chloride BP.....	50 mg
Menthol BP.....	2.5 mg
Excipients.....	q.s.
Approved colour and Flavours added.	

For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Oral Liquid.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indication.

Bromhexine, dextromethorphan and ammonium chloride which relieve dry cough. Bromhexine is a mucolytic which thins and loosens mucus (phlegm), making it easier to cough out. Dextromethorphan is a cough suppressant that relieves cough by reducing the activity of cough centre in the brain. Ammonium chloride is an expectorant which decreases the stickiness of mucus (phlegm) and helps in its removal from the airways. Menthol gives a soothing effect.

4.2 Posology and method of administration.

Oral administration.

Adults, the elderly and children over 12 years: One 10ml measure up to four times daily.

Children under 12 years: Do not use.

4.3 Contraindications

Hypersensitivity to any of the constituents.

4.4 Special warnings and precaution for use.

None stated.

4.5 Interaction with other medicinal product and other forms of interaction.

None known

4.6 Pregnancy and Lactation.

Contraindicated; since Dextromethorphan and Bromhexine are contraindicated in lactation, the combination generic cannot be used in breast feeding mother.

4.7 Effect on the ability to drive and use machine.

Not known.

4.8 Undesirable effect.

The side effects may be associated with the use of this formulation like Rhinorrhoea, Lacrimations, Allergic reactions and Gastric irritation.

4.9 Overdose.

No overdose has been report.

Treatment: Appropriate supportive therapy dependent upon individual response to the preparation.

5 PHARMACOLOGICAL PROPERTIES**5.1 Pharmacodynamic Properties.**

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.

Dextromethorphan hydrobromide is a selective antitussive which raises threshold of cough centre and suppresses the cough reflex by direct action on the cough centre in the medulla. It does not depress mucociliary function of the airway mucosa and is also devoid of constipating and addicting actions.

5.2 Pharmacokinetic Properties.

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.

Absorption: Dextromethorphan well absorbed orally, Metabolism: Extensively metabolized by liver, Excretion: Excreted primarily through urine as metabolites; about 7 to 10% is excreted through faeces.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Methyl Paraben Sodium	BP
Propyl Paraben Sodium	BP
Xanthan Gum	BP
Sorbitol Liquid	BP
Polysorbate 80	BP
Colour Quinoline yellow	In House
Brilliant Blue FCF	In House
Mixed Fruit Flavour	In House
Sucrose	BP
Purified water	BP

6.2 Incompatibilities

unknown

6.3 Shelf-life

36 months

6.4 Special precautions for storage

Do not store above 30°C. Store in a cool dry place.

6.5 Nature and composition of immediate packaging

Light Green transparent viscous liquid with a characteristic flavor packed in 100 ml labelled PET bottle with screw cap, which is further packed in a carton with a leaflet.

6.6 Special precautions for the disposal of unused medicinal products or waste materials

None.

7 MARKETING AUTHORISATION HOLDER

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