

PRODUCT LITERATURE

BROVENT SYRUP 8 MG/ 5 ML

Each 5 ml contains

Bromhexine HCl BP 8 mg

Preservative

Methyl Paraben BP 0.1% w/v
Propyl Paraben BP 0.01% w/v

Product description

Yellow coloured clear syrup with fruity odour and sweet taste.

Pharmacodynamics Properties

Bromhexine is an expectorant/mucolytic agent. The drug is a benzylamine derivative (2-amino-3, 5-dibromo-N-cyclohexyl N-methylbenzylamine hydrochloride) and also a derivative of vasicine and adhatodic acid, alkaloids obtained from the plant Adhatoda vasica.

Following oral administration, bromhexine has increased sputum volume and reduced the viscosity of bronchial secretions in chronic bronchitis patients. The drug has been reported to induce hydrolytic depolymerization of mucoprotein fibers and stimulate activity of the ciliated epithelium. An increase in lysosomal activity facilitated by bromhexine has been postulated. Improvements in pulmonary function in bronchitis patients appear secondary to easier expectoration.

An effect of bromhexine on increasing sputum concentrations of various antibiotics (eg, oxytetracycline, erythromycin, ampicillin, amoxicillin) has also been reported. However, some of these effects (exocrine stimulation, increased sputum concentrations) have not been confirmed in some studies.

It has been suggested that a metabolite of bromhexine, ambroxol, may contribute to enhanced secretion from exocrine glands during bromhexine administration.

Pharmacokinetics Properties

Absorption

Oral, well absorbed
Rapidly absorbed from the gastrointestinal tract
Peak plasma concentrations occur after about 1 hour following oral administration

Metabolism

Bromhexine undergoes extensive first-pass metabolism in the liver:
Ambroxol is a metabolite of bromhexine

Distribution

It is widely distributed to body tissues
Bromhexine is highly bound to plasma proteins
Bromhexine crosses the blood-brain barrier and small amounts cross the placenta.

Excretion

Bromhexine is excreted primarily in the urine as metabolites. Only small amounts appear as unchanged drug.
About 85 to 90% of a dose is excreted in the urine mainly as metabolites. Approximately 70% of an oral dose of bromhexine has been recovered in the urine within 24 hours
Other excretion: faeces, 4%

Elimination Half-life

It has a terminal elimination half-life of 13 to 40 hours

Indication

Reduction of sputum viscosity

Recommended dose

To be taken 3 times a day.

Adult: 5 - 10 ml
Children (6 - 12 years): 2.5 - 5 ml

Route of administration

Oral

Contraindications

Hypersensitivity to bromhexine or other components of the formulation.

Warnings and precautions

Very rare cases of chronically associated severe skin impairments such as Stevens Johnson Syndrome, Toxic Epidermal Necrolysis (TEN), Erythema Multiforme (EM) and Acute Generalized Exanthematous Pustulosis (AGEP) have been reported. In most cases, these could be explained by the severity of the underlying disease or concomitant administration of another drug. In the early stages of such severe skin reactions, initially only nonspecific flu-like symptoms appear, e.g. fever, arthralgia, runny nose, cough, and sore throat. If skin or mucous membrane damage occurs, seek medical advice immediately and discontinue treatment as a precaution.

Patients being treated with bromhexine should be notified of an expected increase in the flow of secretions.

The use of Bromhexine without medical supervision is not intended in patients who suffer from such condition chronically.

Medical advice should be sought if the symptoms last longer than 14 days and/or if the symptoms increase in spite of treatment with bromhexine.

Since mucolytics may disrupt the gastric mucosal barrier bromhexine should be used with care in patients with a history of peptic ulcer disease (gastric ulcer).

Care is also advisable in asthmatic patients.

Clearance of bromhexine or its metabolites may be reduced in patients with severe hepatic or renal impairment.

Bromhexine may increase the amount of antibiotic penetration. Antibiotics are medicines used to treat infections.

Interactions with other medicaments

Bromhexine may increase the concentration of concurrently administered antibiotics in bronchial secretions. No clinically relevant interactions with other medications have been reported

Pregnancy/Reproduction

Pregnancy

There is no data on the use of bromhexine in pregnant women. The effects, if any, on the developing fetus are unknown. Until more information is available, bromhexine should only be used during pregnancy if the maternal condition justifies the potential risk to the fetus.

Lactation

Available evidence and/or expert consensus is inconclusive or is inadequate for determining infant risk when used during breastfeeding. Weigh the potential benefits of drug treatment against potential risks before prescribing this drug during breastfeeding.

Side effects

BROMHEXINE SYRUP 8MG/5ML may cause severe allergy and serious skin reactions. Stop using BROMHEXINE SYRUP 8MG/5ML and seek medical assistance immediately if you experience any of the following symptoms:

- 1) severe allergy: breathing difficulties, light headedness, skin swellings or rash
- 2) severe skin reaction: skin reddening, blisters, rash, fever, sore throat or eye irritation

Dermatologic Effects: urticaria,

Gastrointestinal Effects: nausea, epigastric pain, vomiting, and diarrhoea

Hepatic Effects: Transient elevations in serum aminotransferase levels

Neurologic Effects (Central nervous system): dizziness and headache

Renal Effects: Nocturnal enuresis

Others:

- Anaphylaxis;
- bronchospasm; difficulty in breathing
- angioedema; lips, mouth, tongue or throat which may cause difficulty swallowing or breathing.

ADR: pruritus, overdose

Immune System Disorders

Frequency not known: Anaphylactic reactions including anaphylactic shock.

Skin and Subcutaneous Skin Disorders

Frequency not known: Severe skin reactions (including Stevens Johnson syndrome, Toxic epidermal necrolysis (TEN), Erythema Multiforme (EM) and Acute Generalized Exanthematous Pustulosis (AGEP).

Packing

Packed in plastic container of 120 ml

Storage Condition

Store below 30°C, in a dry place, protected from direct light.

Keep away from reach of children.

Jauhkan daripada kanak-kanak.

SHAKE WELL BEFORE USE

Shelf life

2 years from date of manufacturer

Name and Address of Product Registration Holder/ Distributor:

ZONTRON PHARMACEUTICALS SDN.BHD. (445695-T)

Lot 10 & 11, PERDA Industrial Park,

Lorong IKS Simpang Ampat B,

14100 Simpang Ampat,

S.P.S Pulau Pinang, Malaysia

Name and Address of Manufacturer:

TERAPUTICS SDN. BHD. (590500-W)

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Malaysian Drug Registration No.

MAL19940582XCZ

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