

PACKAGE INSERT TEMPLATE FOR BROMHEXINE TABLET & SYRUP/ELIXIR

Brand or Product Name

[Product name] Tablet 8mg

[Product name] Syrup/Elixir 4mg/5ml

[Product name] Syrup/Elixir 8mg/5ml

Name and Strength of Active Substance(s)

Bromhexine hydrochloridemg

Product Description

[Visual description of the appearance of the product (eg colour etc)]

eg Colourless, raspberry flavoured syrup

White, circular flat beveled edge tablets marked '8' on one side

Pharmacodynamics

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

Absorption

Oral, well absorbed

Rapidly absorbed from the gastrointestinal tract

Peak plasma concentrations occur after about 1 hour following oral administration

Updated October 2011

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

Secretolytic therapy in acute and chronic bronchopulmonary diseases associated with abnormal mucus secretion and impaired mucus transport

Recommended Dosage

Adult Dosage

Bromhexine is usually given orally in a dose of 8 to 16 mg three times daily.

At commencement of treatment, it may be necessary to increase the total daily dose up to 48 mg in adults (initially for 7 days).

Pediatric Dosage

Dosing according to body weight:

0.3 mg/kg/day 8 hourly for 7 days then 0.15 mg/kg/day 8 hourly;

Dosing according to age:

Children 6 - 12 years: 4 mg 3 times daily

Children 2 - 6 years: 2mg 3 times daily

Children under 2 years: 1mg 3 times daily

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Mode of Administration

Oral

Contraindications

Hypersensitivity to bromhexine or other components of the formulation

Warnings and Precautions

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.

Statement on Usage During Pregnancy and Lactation*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.

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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.

Adverse Effects / Undesirable Effects

Dermatologic Effects: skin rash, 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; swelling of the face, lips, mouth, tongue or throat which may cause difficulty swallowing or breathing.

Overdose and Treatment

No symptoms of overdosage have been reported in man to date. If they occur, supportive and symptomatic treatment should be provided

Storage Conditions

[*eg Store below.... °C*]

Dosage Forms and Packaging Available

[*Packaging type & pack size*]

Name and Address of Manufacturer

[*Name & full address of manufacturer*]

Name and Address of Marketing Authorization Holder

[*Name & full address of marketing authorization holder*]

Date of Revision of Package Insert

[*day/month/year*]

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