BISCOMIN TABLETS 8mg

NAME AND STRENGTH OF ACTIVE SUBSTANCE:
Each tablet contains:
Bromhexine Hydrochloride ……8mg

PRODUCT DESCRIPTION:
An orange, scored, flat of diameter 7mm round tablet with 'MPI' logo.

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 increase 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 (e.g., 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.

Distribution

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

Metabolism

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

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 13-40 hours.

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

RECOMMENDED DOSAGE:
This medicine should be taken after food.

Adults Dosage
Bromhexine is usually given orally in a dose of 8-16mg three times daily. At commencement of treatment, it may be necessary to increase the total daily dose up to 48mg in adults (initially for 7 days).

Children 6 - 12 years: 4 mg 3 times daily.

ROUTE 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 incease the amount of antibiotic penetration. Antibiotics are medicines used to treat infections.
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.

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 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.

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:

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)]. Skin rash and urticaria
Gastrointestinal Effects: Nausea, epigastric pain, vomitting and diarrhoea.
Hepatic Effects: Transient elevations in serum aminotransferase levels
Neurologic Effects (Central nervous system): Dizziness and headache
Renal Effects : Nocturnal enuresis
Others:

- Bronchospasm, difficulty in breathing
- Angioedema; swelling of the face, lips, mouth, tongue or throat which may cause difficulty swallowing or breathing.

SYMPTOMS AND TREATMENT OF OVERDOSE:

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

STORAGE CONDITION

Store below 30ºC. Protect from heat and moisture. Keep out of reach of children.

DOSAGE FORMS AND PACKAGING AVAILABLE:

Blister Pack: 100 x 10's

NAME AND ADDRESS OF MANUFACTURER / PRODUCT REGISTRATION HOLDER:

MALAYSIAN PHARMACEUTICAL INDUSTRIES SDN BHD (101323-U)
Plot 14, Lebuhraya Kampung Jawa,11900 Bayan Lepas,
Pulau Pinang, Malaysia.

DATE OF REVISION:

26/06/2018