



BROMHEXINE (CHILDREN) SYRUP

COMPOSITION:
Each 5ml contains
Bromhexine HCl 4mg
Sodium Benzoate 0.1% w/v as preservative.

PRESENTATION:
Colorless to pale-yellowish liquid with fruity flavoured syrup.

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

PHARMACOLOGY:
Mechanism of Action:
Bromhexine HCl is a mucolytic expectorant whose action is to stimulate the mucous glands to produce a secretion which is less viscous and has a reduced content of acid glycoprotein fibres.

Pharmacokinetics:
Bromhexine HCl is rapidly absorbed from the gastrointestinal tract and about 85% to 90% of a dose is excreted in the urine mainly as metabolites. Ambroxol is a metabolite of bromhexine. Bromhexine is highly bound to plasma proteins.

DOSAGE AND ADMINISTRATION:
For oral administration only.
To be taken 3 times a day.
Children under 2 years : 1.25ml (1mg)
Children 2-6 years : 2.5ml (2mg)
Children 7-12 years : 5ml (4mg)
Adult & Children more than 12 years : 10ml (8mg)

CONTRAINDICATION:
None known.

PRECAUTION:
It should be given with caution in patients with history of gastric ulceration. 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.

Use in Pregnancy and Lactation:
No evidence of ill-effects during pregnancy, but the use of drugs during 1st trimester of pregnancy should be observed. Bromhexine HCl is expected to enter breast milk and thus should be avoided during lactation.

SIDE EFFECTS:
Occasional gastrointestinal discomfort may occur, but these are almost invariably mild. There may be a transitory rise in serum transaminase levels in some patients. With continuation of the drug, transaminases return to pretreatment levels, even in those patients with pre-existing impairment of hepatic function.

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).

DRUG INTERACTIONS:
Bromhexine has been shown to enhance the response of erythromycin, cephalixin and amoxycillin.

OVERDOSAGE & TREATMENT:
Cases of overdosage, if occur, should be managed symptomatically.

STORAGE :
Keep container well closed. Store below 30°C. Protect from light.

**KEEP OUT OF REACH OF CHILDREN.
JAUHI DARI KANAK-KANAK.**

PACK QUANTITIES :
Available in 60ml & 100ml PET bottle and 120ml glass bottle. Not all pack sizes may be marketed.

Further information can be obtained from pharmacist, physician or the manufacturer.

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Product Registration Holder & Manufactured By :
 **Kotra Pharma (M) Sdn. Bhd.**
No 1, 2 & 3, Jalan TTC 12, (60002-V)
Cheng Industrial Estate,
75250 Melaka, Malaysia.

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