BioWell BMUSOL TABLET 30MG

VIBMUxx-05

DESCRIPTION
Round, white uncoated tablet, flat bevel-edged, with break bar line on one side and plain on the other side.

COMPOSITION
Ambroxol hydrochloride 30 mg.

PHARMACODYNAMICS
Ambroxol is a metabolite of bromhexine and is used similarly as a mucolytic. Preclinically, ambroxol has been shown to increase respiratory tract secretion. It enhances pulmonary surfactant production and stimulates ciliary activity. These actions result in improved mucus flow and transport (mucociliary clearance). Improvement of mucociliary clearance has been shown in clinical pharmacologic studies. Enhancement of fluid secretion and mucociliary clearance facilitates expectoration and eases cough.

PHARMACOKINETICS
Ambroxol hydrochloride is completely absorbed after oral administration. It reaches maximum plasma concentration 9 to 10 hours. Time to peak concentration after oral administration is approximately two hours. After oral administration, 85% of the active substance is eliminated in the urine.

INDICATIONS
Secretolytic treatment for acute & chronic bronchopulmonary disease associated with abnormal mucus secretion & impaired mucus transport.

DOSAGE AND ADMINISTRATION
For oral use.
The recommended dose for adults is 1 tablet 3 times daily. The therapeutic effect may be enhanced by administering 2 tablets twice daily and should be taken after meals with liquid.

CONTRAINDICATIONS
Hypersensitivity to ambroxol or other components of the formulation.

WARNINGS AND PRECAUTIONS
- Medical advice should be sought for patients with liver and kidney problems before taking this medication.
- Special care is recommended during the first three months of pregnancy. Risk-benefits should be considered against possible effects on the child.
- Do not use ambroxol hydrochloride if allergic to ambroxol or to any of the other ingredients in Presmedic Ambroxol. Consult doctor or pharmacist of any allergies.
- Ambroxol may increase the amount of antibiotic penetration.
- Be aware that all the medicines carry some risks and that all possible risks may not be known at this stage despite thorough testing.
- Medical advice should be sought if the symptoms last longer than 14 days and/or if the symptoms increase in spite of the treatment.
- If any concerns about the effects of taking ambroxol, consult doctor's advice.
- 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.

DRUG INTERACTIONS
- Ambroxol administered together with antibiotics such as amoxicillin, cefuroxime, erythromycin, doxycycline will lead to higher antibiotic concentration in the lung tissue.
- No clinically relevant unfavourable interaction with other medications have been reported.

PREGNANCY AND LACTATION
Use in pregnancy
Preclinical studies as well as extensive clinical experience after the 28th week have shown no evidence of ill-effects during pregnancy. Nonetheless, the usual precautions regarding the use of drugs during pregnancy, especially during the 1st trimester, should be observed.

Use in lactation
For breastfeeding or likely to breastfeed during course of medication, consult doctor's advice. The risk-benefits of ambroxol must be assessed against possible effects on your child. This medication should be used only if absolutely necessary during lactation.

SIDE EFFECTS
- Mild upper gastrointestinal side effects such as primarily pyrosis, dyspepsia and occasionally nausea, vomiting, diarrhea, bloated feeling have been reported, principally following parenteral administration.
- Allergic reactions, primarily skin rashes, difficulty in breathing, swelling of the face, lips, mouth, tongue or throat which may cause difficulty swallowing or breathing have occurred rarely.
- Reports of severe acute anaphylactic-type reactions but their relationship to ambroxol is uncertain and are extremely rare case.
- *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).

SYMPTOMS AND TREATMENT OF OVERDOSE
Symptoms
No symptoms of overdosage have been reported.

Treatment
If symptoms occur, treatment should be provided by doctor or pharmacist.

EFFECTS ON ABILITY TO DRIVE AND USE MACHINE
There is no evidence from postmarketing data for an effect on the ability to drive and use machines. Studies on the effects on the ability to drive and use machines have not been performed.

Note: The information given here is limited. For further information, consult your doctor or pharmacist.

Storage: Store below 30°C.

Presentation/Packing: Blister pack of 10 x 10's.

Manufactured by: **Hovid Bhd,**
Lot 56442, 7 ½ Miles, Jalan Ipoh / Chemor,
31200 Chemor, Perak, Malaysia.

Distributor: **SSJ Pharma Sdn. Bhd.**
658-D, Jalan Bukit Melaka 1/1, Taman Bukit Melaka,
Bukit Beruang, Bukit Baru, 75450 Melaka Tengah,
Melaka, Malaysia.

Product registration holder: **Hovid Nutriworld Sdn Bhd,**
121, Jalan Tunku Abdul Rahman, 30010 Ipoh,
Perak, Malaysia.

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