BROMHEXINE HYDROCHLORIDE

BROMUCOL

4 mg per 5 mL SYRUP

MUCOLYTIC

FORMULATION:
Each 5mL (one teaspoonful) contains:
Bromhexine Hydrochloride ..... 4 mg

DESCRIPTION:
Bromhexine is a mucolytic used in the treatment of pulmonary disorders associated with productive cough characterized by the presence of sputum and may be associated with condition such as chronic bronchitis, bronchiectasis, or cystic fibrosis.
BROMUCOL is the Brand Name of your Medicine (Bromhexine) is a clear, Red Syrupy Liquid with strawberry falvor. Boston Round Amber Glass Bottle x 60 mL and 120 mL with Aluminum Pilfer Proof Cap and Foam Polyethylene Liner (Box of 1 s).

WHAT IS IN THE MEDICINE?
Bromhexine Oral Liquid contains bromhexine hydrochloride, which thins and loosens mucus to help clear chest congestion which relieves chesty coughs and breathing difficulties due to excess mucus in cold, flu and respiratory tract infections.
Bromhexine is a mucolytic used in the treatment of pulmonary disorders associated with productive cough characterized by the presence of sputum and may be associated with condition such as chronic bronchitis, bronchiectasis, or cystic fibrosis.

STRENGTH OF THE MEDICINE : See Formulation

WHAT IS THIS MEDICINE USED FOR?
BROMUCOL (Bromhexine) is used in Secretolytic therapy in acute and bronchopulmonary disease associated with abnormal mucus secretion and impaired mucus transport.
BROMUCOL (Bromhexine) has also been used orally in the treatment of dry eyes syndrome associated with abnormal mucus production.

HOW MUCH AND HOW OFTEN SHOULD YOU USE THIS MEDICINE?
Adults and Children over 12 years old: 10 mL (2 teaspoonfuls) three times a day.
Children 7 to 12 years old: 5 mL (1 teaspoonful) three times a day.
2 to 6 years old: 2.5 mL (1/2 teaspoonful) three times a day.
1 to 2 years old: 1.25 mL (1/4 teaspoonful) three times a day.
Or as prescribed by the physician. Take immediately after meals.

WHEN SHOULD YOU NOT TAKE THIS MEDICINE?
Do not take **BROMUCOL** Oral Liquid if you are allergic to bromhexine or to any of the other ingredients in **BROMUCOL** Oral Liquid.

CARE THAT SHOULD BE TAKEN WHEN TAKING THIS MEDICINE?
Since mucolytics may disrupt the gastric mucosal barrier bromhexine may be used with care in patients with history of peptic ulcer diseases. Care is also advisable in asthmatic patients. Clearance of bromhexine or its metabolites may be reduced in patients with severe hepatic or renal impairment.

UNDESIRABLE EFFECTS OF THIS MEDICINE:
Gastrointestinal effects may occur occasionally with bromhexine and a t ransient rise in serum aminotransferase values has been reported. Other reported adverse effects include headache, dizziness, sweating, and skin rashes. Inhalation of bromhexine has occasionally produced cough or bronchospasm in susceptible subject.

WHAT OTHER MEDICINE OR FOOD SHOULD BE AVOIDED WHILE TAKING THIS MEDICINE?
Inform your doctor or pharmacist if you are taking any antibiotics as bromhexine may increase the absorption of antibiotics or if you are planning to take other medications, nutritional supplements, or herbal products.

WHAT SHOULD YOU DO IF YOU MISS A DOSE?
If you forget a dose, take it as soon as you remember it. However, if it is nearly time for the next dose, skip the missed dose and continue with your regular dosing schedule.
Do not take a double dose at any one time

SIGNS AND SYMPTOMS OF OVERDOSE:
• skin rashes, including pinkish, itchy swellings (also called hives)
• difficulty in breathing
• swelling of the face, lips, mouth, tongue or throat which may cause difficulty swallowing or breathing.

WHAT TO DO WHEN YOU HAVE TAKEN MORE THAN THE RECOMMENDED DOSAGE?
If you have taken too much **BROMUCOL** Immediately telephone your doctor, pharmacist or the Poisons Information Centre.

PHARMACOKINETICS:
Bromhexine Hydrochloride is rapidly absorbed from the gastrointestinal tract; peak plasma concentration occurs after about 1 hour. Bromhexine undergoes extensive first - pass metabolism in the liver: its oral bioavailability is stated to be only about 20%. It is widely distributed to body tissues. About 85% t o 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. It has terminal elimination half-life of 13 to 40 hours. Bromhexine crosses the blood-brain barrier and small amounts cross the placenta.

HOW SHOULD YOU KEEP THIS MEDICINE
Store at temperatures not exceeding 30°C

WHEN SHOULD YOU CONSULT YOUR DOCTOR?
Tell your doctor or pharmacist as soon as possible if you experience any side effects during or after taking **BROMUCOL** Oral Liquid, so that these may be properly treated.
You should tell your doctor or pharmacist if you notice anything unusual, during or after taking **BROMUCOL** Oral Liquid.

ADR REPORTING STATEMENT:
For suspected adverse drug reaction, report to FDA : www.fda.gov.ph Patient must seek medical attention immediately at the first sign of any adverse drug reactions.

AVAILABILITY:
Boston Round Amber Glass bottle x 60 mL and 120 ml with Aluminum Pilfer Proof Cap and Foam Polyethylene Liner (Box 1 s)

Reference : Martindale 36th Edition

SHELF-LIFE: 36months

REGISTRATION NO. : DRP- 8755

DATE OF THE FIRST AUTHORIZATION/INITIAL OF THE AUTHORIZATION
13 March 2020

DATE OF REVISION OF PATIENT INFORMATION LEAFLET
08 August 2020

Manufactured by:
SAN MARINO *Laboratories* **CORP.**
#1 Crisanto delos Reyes Street
Brgy. Javalera, Gen. Trias, Cavite