

**AMBROXOL**  
**Hydrochloride**  
**BROLOXIN**

6 mg/mL Syrup  
(Oral Drops)  
Mucolytics

**Description of the Product**

Clear colorless cherry flavored syrup with sweet and slightly bitter after taste containing 6 mg of Ambroxol hydrochloride in each mL.

**What is in the medicine?**

Ambroxol is a metabolite of bromhexine and is used similarly as a mucolytic. It is given in a usual oral daily dose of 60 to 120 mg of the hydrochloride in 2 divided doses. Ambroxol has also been given by inhalation, injection or rectally.

**Strength of the Medicine**

Each mL contains:  
Ambroxol Hydrochloride, PP1.....6 mg

**What is this Medicine used for?**

Acute and chronic disorders of the respiratory tract associated with pathologically thickened mucus and impaired mucus transport.

**How much and how often should you use this medicine**

INFANTS  
1-2 years old:  
1.25 mL (two times a day)  
7-12 months old:  
1.0 mL (two times a day)  
0-6 months old:  
0.5 mL (two times a day)  
Or as prescribed by a physician.

**When should you not take this Medicine?**

In a very small number of cases, there have been reports of severe skin reactions such as Stevens-Johnson syndrome and toxic epidermal necrolysis (TEN) occurring in temporal association with the use of expectorants such as ambroxol hydrochloride. Most of these cases were attributable to the underlying disease and/or to other medication being taken concomitantly. In addition, during the early phase of Steven-Johnson syndrome or TEN, patients may initially experience non-specific influenza-like symptoms such as fever, joint pain, rhinitis, cough and sore throat. Because of these non-specific influenza-like symptoms, symptomatic treatment with cough and cold medications, which is inappropriate, may be started. If new skin mucosal lesions appear, therefore, medical advice should be sought immediately and the use of ambroxol hydrochloride discontinued.

**Patients with impaired kidney or liver function.**

If you have impaired kidney function or severe liver disease, you must not take ambroxol hydrochloride except on medical advice. With ambroxol, as with any medicine which is broken down in the liver and then eliminated via the kidneys, accumulation of the breakdown products which are formed in the liver can be expected to occur in patients with severely impaired kidney function.

In some rare bronchial diseases which are associated with excessive accumulation of secretions (such as primary ciliary dyskinesia), ambroxol hydrochloride should only be used under medical supervision because of the risk that secretions may accumulate.

**Undesirable Effects of this Medicine**

**Immune system disorders / Skin and subcutaneous tissue disorders**

**Rare:** Skin rash, urticaria (nettle rash)  
**Not known:** Swelling of the skin and mucous membranes, itching, anaphylactic reactions (severe allergic reactions), including shock, other hypersensitivity reactions.

**Nervous system disorders**

**Common:** Nausea, feeling of numbness in the mouth  
**Uncommon:** Vomiting, diarrhoea, indigestion, abdominal pain, dry mouth  
**Rare:** Dry throat  
**Very rare:** Constipation, increased salivation

**Respiratory, thoracic and mediastinal disorders**

**Common:** Feeling of numbness in the throat  
**Very rare:** Increased nasal discharge  
**Not known:** Shortness of breath (as symptom of a hypersensitivity reaction)

**Renal and urinary disorders**

**Very rare:** Difficulty urinating

**General disorders and administration site conditions**

**Uncommon:** Fever, mucous membrane reactions

**What other medicine or food should be avoided while taking this medicine?**

Simultaneous use of ambroxol hydrochloride and cough suppressants may lead to the development of a dangerous accumulation of secretions owing to reduction of the cough reflex and should be undertaken only after careful risk-benefit assessment.

**What should you do if you miss a dose?**

If you forget to take ambroxol hydrochloride or take too small a dose, wait until it is time to take your next dose and then continue taking ambroxol hydrochloride as described in the dosage instructions above.

**What to do when you have taken more than the recommended dosage?**

No specific symptoms of overdose have been reported to date. The symptoms observed in cases of accidental overdose or medication error consistent with the side effects which may occur at recommended doses. In case of overdose, please consult your doctor as symptomatic treatment may be required.

**How should you keep this medicine?**

Store at room temperatures not exceeding 30°C.

**AVAILABILITY**

Amber Glass Bottle x 15 mL with Medicine Dropper (Box of 1's)

**ADR REPORTING STATEMENT**

"For suspected adverse drug reaction, report to the FDA:www.fda.gov.ph"  
Seek medical attention immediately at the first sign of any adverse drug reaction.

**Registration Number**

DRP-1206

**Date of First Authorization/ Renewal of the Authorization**

May 23, 2012

**Date of Revision of Patient Information Leaflet**

JULY 2021



170 mm

105 mm



INSERT Required size:  
105mm x 170mm  
Required folding:  
2 Folds crosswise (facing the text)

