

PACKAGE INSERT

SCHEDULING STATUS

§ 2

PROPRIETARY NAME AND DOSAGE FORM

BRNCOL COUGH LINCTUS Syrup

COMPOSITION

Each 10 ml contains:

| | |
|---------------------------------------|-----------|
| Dextromethorphan hydrobromide | 30,0 mg |
| Ammonium chloride | 180,0 mg |
| Panthenol | 100,0 mg |
| Preserved with methyl hydroxybenzoate | 0,10% m/v |

PHARMACOLOGICAL CLASSIFICATION

A 10.1 Antitussives and Expectorants

PHARMACOLOGICAL ACTION

BRNCOL COUGH LINCTUS provides the specific cough suppressing action of Dextromethorphan hydrobromide plus the expectorant effect of ammonium chloride. Dextromethorphan hydrobromide is a well-tolerated powerful cough suppressant with an action similar to that of codeine but with the important advantage of not being a narcotic. It is centrally acting with a direct action on the cough centre in the medulla. It could stop bronchial cough for up to 8 hours on a single dose. Ammonium Chloride promotes the liquefaction of mucosal secretions and facilitates expectoration.

INDICATIONS

Relief of productive or non-productive bronchial cough in colds, bronchitis and other respiratory tract disorders.

CONTRA-INDICATIONS

BRNCOL COUGH LINCTUS should not be given to children under the age of 2 years, and to those persons known to be hypersensitive to any of the substances in its composition.

Ammonium salts are contra-indicated-in patients with hepatic or renal impairment.

Dexpanthenol is contra-indicated in haemophiliacs and in patients with ileus due to mechanical obstruction.

INTERACTIONS

Special care should be taken when **BRNCOL COUGH LINCTUS** is concomitantly taken with amiodarone, fluoxetine, haloperidol, paroxetine, propafenone, quinidine, and thioridazine, central nervous system (CNS) depressants.

Severe and sometimes fatal reactions have been reported after use of dextrometorphan in patients receiving monoamine oxidase inhibitors (MAOI's) furazolidone, phenelzine, procarbazine, selegiline, tranylcypromine). Taking **BRNCOL COUGH LINCTUS** when taking MAO inhibitors or have taken them within the past 2 to 3 weeks may cause coma, dizziness, excited or unusual behavior, fever, high blood pressure, nausea, sluggishness, spasms, and tremors.

Smoking tobacco—Since **BRNCOL COUGH LINCTUS** decreases coughing, it makes it difficult to get rid of the mucus that may collect in the lungs and airways resulting from smoking.

PREGNANCY AND LACTATION

The safety of this preparation in pregnancy and lactation has not been established.

DOSAGE AND DIRECTIONS FOR USE

Adults: 10 ml two to four times daily

Children (over 2 years): 2,5 to 5 ml according to age two to four times daily

BRNCOL COUGH LINCTUS may be taken neat or diluted with water, milk, tea, fruit juices, etc., preferably after meals.

SIDE-EFFECTS AND SPECIAL PRECAUTIONS

Dextromethorphan hydrobromide occasionally causes drowsiness and gastro-intestinal upsets. The established medical principle of prescribing medicaments in early pregnancy, only when absolutely indicated, should be observed.

KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENT

Clinical symptomatology may include one or more of the following: Tiredness, drowsiness, apathy, rigor, miosis and respiratory depression.

Treatment includes gastric lavage with abundant activated charcoal followed by sodium sulphate in black coffee. A high enema may be useful. Analeptics and assisted respiration may be required.

IDENTIFICATION

A clear brown syrup with a liquorice odour.

PRESENTATION

BRNCOL COUGH LINCTUS is packed in 100 ml or 200 ml amber glass bottles with white plastic closures. The bottles are packed into a carton.

STORAGE INSTRUCTIONS

Store below 25 °C in a dark place.

KEEP OUT OF REACH OF CHILDREN.

REGISTRATION NUMBER

G 0931 (Act 101/1965)

Benoni

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