

BRNCOLIN HONEY EUCALYPTUS- menthol lozenges
BRNCOLIN, S.A. de C.V.

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

CghDrpMnthlHnyEucllyptsBrncIn

Active Ingredient

Menthol 7.5mg

Purpose

Cough Suppressant/Oral Anesthetic

Uses

temporarily relieves •Cough due to minor and bronchial irritation occurring with a cold or inhaled irritants •occasional minor irritation and sore throat

Warnings

Sore throat warning: If sore throat is severe •persists for more than 2 days • is accompanied or followed by fever, headache, rash, swelling, nausea, or vomiting, consult a doctor promptly. These symptoms may be serious.

Ask a doctor before use if you have

- persistent or chronic cough such as occurs with smoking, asthma, or emphysema
- cough accompanied by excessive phlegm (mucus)

When using this product

- do not exceed recommended dosage

Stop use and ask a doctor if

- cough persists for more than 7 days, tends to recur, or is accompanied by fever, rash, or persistent headache. These could be signs of a serious condition. •sore throat is severe or irritation, pain, or redness lasts or worsens •sore mouth does not improve in 7 days.

Keep out of reach of children

if pregnant or breast feeding ask a Health Professional before using

Directions

- adults and children 6 years and older: dissolve 1 drop slowly in the mouth. May be repeated every hour as needed or as directed by a doctor
- children under 6 years: ask a doctor.

Inactive Ingredients

Citric Acid, Elderberry flower extract, Eucalyptus leaf extract, Eucalyptus oil leaf extract, Glucose, Honey, Mullein flower extract, Sugar

Package Label

BRONCOLIN HONEY EUCALYPTUS			
menthol lozenge			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:62583-002

Route of Administration ORAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	7.5 mg

Inactive Ingredients

Ingredient Name	Strength
CITRIC ACID ACETATE (UNII: DSO12WL7AU)	
SAMBUCUS NIGRA FLOWER (UNII: 07V4DX094T)	
EUCALYPTUS PIPERITA LEAF (UNII: 4GG3SCZ7GT)	
EUCALYPTUS OIL (UNII: 2R04ONI662)	
DEXTROSE (UNII: IY9XDZ35W2)	
HONEY (UNII: Y9H1V576FH)	
VERBASCUM DENSIFLORUM FLOWER (UNII: N7FC535Q3R)	
SUCROSE (UNII: C151H8M554)	

Product Characteristics

Color	yellow (Amber)	Score	no score
Shape	ROUND (Lozenge)	Size	17mm
Flavor	HONEY (Honey and Eucalyptus)	Imprint Code	B
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:62583-002-22	22 in 1 BAG; Type 0: Not a Combination Product	04/01/2015	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	M012	04/01/2015	

Labeler - BRNCOLIN, S.A. de C.V. (812946390)

Establishment

Name	Address	ID/FEI	Business Operations
BRNCOLIN, S.A. de C.V.		812946390	manufacture(62583-002)