

BRNCOLIN HERBAL EXTRACTS AND HONEY- menthol lozenge
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.

CghDrpMnthlHrbIHnyBrncIn

Active Ingredient

Menthol 7.5mg

Purpose

Cough Suppressant/Oral Anesthetic

Uses

temporarily relieves •cough due to minor and bronchial 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 over: 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, Eucalyptus leaf, Eucalyptus oil, Glucose, Honey, Mullein flower, Propolis, Sugar

Package Label



Drug Facts
(Continued)
Información del Medicamento
(Continúa)

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.
Indicaciones • adultos y niños mayores de 6 años: disolver lentamente 1 pastilla en la boca. Repita cada hora como lo necesite o como recomienda el Doctor • niños menores de 6 años: consulte al Doctor.

Inactive Ingredients
Citric acid, Elderberry flower, Eucalyptus leaf, Eucalyptus oil, Glucose, Honey, Mullein flower, Propolis, Sugar.
Ingredientes inactivos
Aceite de Eucalipto, Acido cítrico, Azúcar, Gordolobo, Glucosa, Miel de abeja, Propóleo, Sáuco.

Made in Mexico by /
Hecho en México por:
BRONCOLIN, S.A. DE C.V.

Imported in USA by/
Importado en USA por:
Midway Importing, Inc.
1807 Britton Road,
Houston, Texas 77043
Tel (713) 802-9363 Fax
(713) 802-9366

BRONCOLINTM
Herbal Extracts & Honey
Extractos Herbales y Miel de Abeja

BRONCOLINTM
Herbal Extracts & Honey
Extractos Herbales y Miel de Abeja

Menthol Cough Suppressant and Oral anesthetic
Calmante de la tos y Anestésico Oral Sabor Mentol

Temporarily calms cough Soothes Sore Throats
Calma temporalmente la tos Alivia la garganta irritada

16 DROPS
16 PASTILLAS

Drug Facts / Información del Medicamento

Active ingredient / Ingrediente Activo Purpose / Uso
Menthol / Mentol 7.5mg.....Cough Suppressant / Oral Anesthetic / Calmante de la tos / Anestésico Oral

Uses temporarily relieves • Cough due to minor and bronchial irritation occurring with a cold or inhaled irritants • occasional minor irritation and sore throat / **USOS** Alivia temporalmente • la tos debido a irritaciones leves en garganta y bronquios causados por el frío e irritantes inhalados • irritación temporal y molestias leves en garganta.

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. / **Precauciones para la garganta irritada:** Si la molestia en la garganta es severa, *persiste por mas de 2 días, *es acompañada o seguida de fiebre, dolor de cabeza salpudido hinchazon, nausea o vomito, consulte al Doctor de inmediato. Estos sintomas pueden ser graves.

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). / **Consulte al doctor antes de usarlo si usted presenta** • tos persistente o crónica como ocurre al fumar, asma o enfisema • tos acompañada de flema excesiva.

When using this product • do not exceed recommended dosage / **Cuando consuma este producto** • no exceda la dosis recomendada.

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. / **Detenga su uso y pregunte al Doctor si** • la tos persiste por mas de 7 días, si tiende a recurrir, o es acompañada de fiebre, salpudido, o dolor de cabeza persistente. Estos podrian ser signos de una situación grave. • molestia severa de garganta, o irritación, dolor o enrojecimiento que perdure o empeore • molestias bucales que no mejoren en 7 días.

Keep out of reach of children if pregnant or breast feeding ask a Health Professional before using. / **Mantenga fuera del alcance de niños, si está embarazada o en lactancia** pregunte a un profesional de la salud antes de consumirlo.

BRONCOLIN HERBAL EXTRACTS AND HONEY

menthol lozenge

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:62583-001
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)	
PROPOLIS WAX (UNII: 6Y8XYV2NOF)	
SUCROSE (UNII: C151H8M554)	

Product Characteristics

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

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:62583-001-16	16 in 1 BOX; Type 0: Not a Combination Product	04/01/2014	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	M012	04/01/2014	

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

Establishment

Name	Address	ID/FEI	Business Operations
BRNCOLIN, S.A. de C.V.		812946390	manufacture(62583-001)

Revised: 10/2022

BRNCOLIN, S.A. de C.V.