

FREEGELLS COUGH DROPS MENTHOL 80CT- menthol lozenge
R.L. ALBERT & SON, INC

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.

Drug Facts

Active ingredient

Menthol 5.4 mg

Purpose

Cough Suppressant / Oral anesthetic

Use

Temporarily relieves:

- cough as may occur with a cold
- occasional minor irritation and sore throat

Warning

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. if sore mouth symptoms do not improve in 7 days, see your dentist or 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)

stop use and ask 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

If pregnant or breast-feeding, ask a health professional before use.

Keep out of reach of children

Directions

Adults and children 5 years and over

dissolve 1 lozenges slowly in mouth. Repeat every 2 hours as needed or as directed by a doctor

children under 5 years , ask a doctor

Other information

- 11 calories per drop
- do not use if bag is torn or open
- **Contains : Soy**

Inactive ingredients

Corn Syrup, eucalyptus oil, FD&C blue no. 1, FD&C red no.40, gum Arabic, maltodextrin, natural flavor, soy lecithin, sucrose and water

Product label

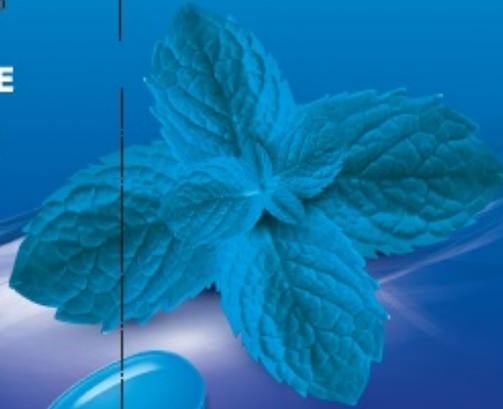
RESEALABLE BAG

TEAR HERE ▶

FREEGELLS COUGH DROPS

Menthol 5.4mg per drop

**SOOTHES SORE
THROATS**
**TEMPORARILY
RELIEVES
COUGHS**



**COUGH
SUPPRESSANT
ORAL ANESTHETIC**

**MENTHOL
EUCALYPTUS**

80 DROPS

001951 000

FREEGELLS COUGH DROPS

Drug Facts	
Active ingredient (in each drop)	Purpose
Menthol 5.4 mg	Cough suppressant/ Oral anesthetic
Uses temporarily relieves:	
<ul style="list-style-type: none"> ■ cough as may occur with a cold ■ occasional minor irritation and sore throat 	
Warnings	
<p>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. If sore mouth symptoms do not improve in 7 days, see your dentist or doctor promptly. These symptoms may be serious.</p>	
Ask a doctor before use if you have:	
<ul style="list-style-type: none"> ■ persistent or chronic cough such as occurs with smoking, asthma, or emphysema ■ cough accompanied by excessive phlegm (mucus) 	
Stop use and ask doctor if	
<ul style="list-style-type: none"> ■ 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 	
<p>If pregnant or breast-feeding, ask a health professional before use. Keep out of reach of children.</p>	
Directions	
adults and children 5 years and over	dissolve 1 lozenge slowly in mouth. Repeat every 2 hours as needed or as directed by a doctor.
children under 5 years	ask a doctor
Other information ■ 11 calories per drop ■ do not use if bag is torn or open ■ Contains: Soy.	
Inactive ingredients: corn syrup, eucalyptus oil, FD&C blue no. 1, FD&C red no. 40, gum arabic, maltodextrin, natural flavor, soy lecithin, sucrose and water.	

Made in Brazil by Riclan S.A.

In USA:
Distributed by:
R.L. Albert & Son, Inc.,
Stamford, CT 06902
Sole Importers U.S.A.



FREEGELLS COUGH DROPS MENTHOL 80CT

menthol lozenge

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:83002-004
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	5.4 mg

Inactive Ingredients

Ingredient Name	Strength
SUCROSE (UNII: C151H8M554)	

CORN SYRUP (UNII: 9G5L16BK6N)	
EUCALYPTOL (UNII: RV6J6604TK)	
LECITHIN, SOYBEAN (UNII: 1DI56QDM62)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
ACACIA (UNII: 5C5403N26O)	
MALTODEXTRIN (UNII: 7CVR7L4A2D)	

Product Characteristics

Color	blue	Score	no score
Shape	OVAL	Size	20mm
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:83002-004-01	6 in 1 CARTON	07/05/2023	
1		80 in 1 BAG; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	07/05/2023	

Labeler - R.L. ALBERT & SON, INC (005900899)

Revised: 7/2023

R.L. ALBERT & SON, INC