FREEGELLS COUGH DROPS MENTHOL STRAWBERRY 30 DROPSmenthol suspension/ drops 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 2.7mg

Purpose

Cough Suppressant / Oral anesthetic

Use

- 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 accompanined 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.

Directions

Adults and children 5 years and over

dissolve 2 lozenges (one at a time) 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

Citric acid, corn syrup, eucalyptus oil, FD&C red no. 40, natural & artificial flavoring, soy lecithin, sucrose and water.

Product label

FREEGELLS COUGH DROPS

Menthol 2,7mg per drop

SOOTHES SORE THROATS TEMPORARILY RELIEVES COUGHS



COUGH SUPPRESSANT ORAL ANESTHETIC

STRAWBERRY

30 DROPS

FREEGELLS COUGH DROPS

Drug Facts

Active ingredient (in each drop)

Purpose

Menthol 2.7 mg.....Cough suppressant/ Oral anesthetic

Uses temporarily relieves:

- cough as may occur with a cold
- 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. If sore mouth symptoms do not improve in 7 days, see your dentist or doctor promptly. These symptoms may be serious.

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- 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 2 lozenges (one at a time) 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: citric acid, corn syrup, eucalyptus oil, FD&C red no.40, natural & artificial flavoring, 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 STRAWBERRY 30 DROPS

menthol suspension/ drops

Product Information

Product Type HUMAN OTC DRUG Item Code (Source) NDC:83002-001

Route of Administration ORAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	2.7 mg

Inactive Ingredients			
Ingredient Name	Strength		
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)			
CORN SYRUP (UNII: 9G5L16BK6N)			
EUCALYPTUS OIL (UNII: 2R04ONI662)			
FD&C RED NO. 40 (UNII: WZB9127XOA)			
HYDROGENATED SOYBEAN LECITHIN (UNII: H1109Z9J4N)			
SUCROSE (UNII: C151H8M554)			
WATER (UNII: 059QF0KO0R)			

Product Characteristics			
Color	pink	Score	
Shape	OVAL	Size	15mm
Flavor	STRAWBERRY	Imprint Code	
Contains			

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:83002-001- 01	9 in 1 CARTON	11/15/2022	
1		30 in 1 BAG		
1		1 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	11/15/2022	

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

Establishment				
Name	Address	ID/FEI	Business Operations	
Riclan S.A.		911989788	manufacture(83002-001)	

Revised: 11/2022 R.L. ALBERT & SON, INC