# FREEGELLS COUGH DROPS MENTHOL 30CT- 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 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.

## 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**



# FREEGELLS COUGH DROPS

## **Drug Facts**

Active ingredient (in each drop)

Purpose .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.

#### Ask a doctor before use if you have:

- persistent or chronic cough such as occurs with smoking, asthma,
- cough accompanied by excessive phiegm (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.

<b>Directions</b>	dissolve 1 lozenge slowly in
adults and children	mouth. Repeat every 2 hours as
5 years and over	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: com syrup, eucalyptus oil, FD&C blue no. 1, FD&C red no. 40, gum arabic, maltodextrin, natural flavor, soy ecithin, 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 30CT

menthol lozenge

#### **Product Information Product Type** HUMAN OTC DRUG Item Code (Source) NDC:83002-005 **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			

P	Packaging			
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:83002-005- 01	9 in 1 CARTON	07/05/2023	
1		30 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