

GEMS MENTHOL EUCALYPTUS- menthol lozenge
Riclan S.A.

Gems 44-173

Active ingredient (in each drop)

Menthol 8.4 mg

Purpose

Cough suppressant/oral anesthetic

Uses

temporarily relieves:

- cough due to a cold
- occasional minor irritation or sore throat

Warnings

Sore throat warning: Severe or persistent sore throat or sore throat accompanied by high fever, headache, rash, swelling, nausea, or vomiting may be serious. Consult a doctor promptly. Do not use more than 2 days unless directed by a doctor.

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 a doctor if

- sore mouth does not improve in 7 days
- cough persists for more than 1 week, tends to recur, or is accompanied by fever, rash, or persistent headache. These could be signs of a serious condition.
- irritation, pain, or redness persists or worsens

Keep out of reach of children.

Directions

- **do not take more than directed**
- adults and children 5 years and over: dissolve 1 drop slowly in the mouth. Repeat every 2 hours as needed.
- children under 5 years: ask a doctor

Other information

- 12 calories per drop

- **Contains: SOY**

Inactive ingredients

corn syrup, eucalyptus oil, FD&C blue #1, FD&C red #40, gum arabic, maltodextrin, natural flavor, soy lecithin, sucrose, water

Principal display panel

Menthol • Cough Suppressant • Oral Anesthetic

Gems™

**MENTHOL
EUCALYPTUS
FLAVOR**

9 DROPS

Distributed by **Gems™ Drops, LLC,**
Hauppauge, NY 11788 **1-844-632-7898**

Drug Facts (continued)		 3 71165 17302 2
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Menthol • Cough Suppressant • Oral Anesthetic		
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Active ingredient (in each drop)	Purpose	• cough accompanied by excessive phlegm (mucus)
Menthol 8.4 mg	Cough suppressant/oral anesthetic	Stop use and ask a doctor if • sore mouth does not improve in 7 days • cough persists for more than 1 week, tends to recur, or is accompanied by fever, rash, or persistent headache. These could be signs of a serious condition. • irritation, pain, or redness persists or worsens
Uses temporarily relieves: • cough due to a cold • occasional minor irritation or sore throat		Keep out of reach of children.
Warnings		Directions • do not take more than directed • adults and children 5 years and over: dissolve 1 drop slowly in the mouth. Repeat every 2 hours as needed.
Sore throat warning: Severe or persistent sore throat or sore throat accompanied by high fever, headache, rash, swelling, nausea, or vomiting may be serious. Consult a doctor promptly. Do not use more than 2 days unless directed by a doctor.		
Ask a doctor before use if you have • persistent or chronic ▶		

Gems 44-173

GEMS MENTHOL EUCALYPTUS

menthol lozenge

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:71165-173
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	8.4 mg

Inactive Ingredients

Ingredient Name	Strength
CORN SYRUP (UNII: 9G5L16BK6N)	
EUCALYPTUS OIL (UNII: 2R04ONI662)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
ACACIA (UNII: 5C5403N26O)	
MALTODEXTRIN (UNII: 7CVR7L4A2D)	
LECITHIN, SOYBEAN (UNII: 1DI56QDM62)	
SUCROSE (UNII: C151H8M554)	
WATER (UNII: 059QF0KO0R)	

Product Characteristics

Color	blue	Score	no score
Shape	SQUARE	Size	18mm
Flavor	MENTHOL (MENTHOL EUCALYPTUS)	Imprint Code	G
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:71165-173-02	9 in 1 PACKAGE; Type 0: Not a Combination Product	09/13/2021	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M012	09/13/2021	

Labeler - Riclan S.A. (911989788)

