

THE ORIGINAL NATURAL HERB COUGH DROPS- menthol lozenge

Ricola Ag

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.

THE ORIGINAL NATURAL HERB COUGH DROPS COUGH SUPPRESSANT THROAT DROPS

Drug Facts

Purpose

Cough suppressant, Oral anesthetic

Active Ingredient (in each drop)

Menthol, 4.8 mg

Uses

temporarily relieves:

- cough due to a cold or inhaled irritants
- occasional minor irritation and pain due to sore throat or sore mouth

Warnings

Sore throat warnings:

- 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 may be serious.
- do not use in children under 6 years of age unless directed by a doctor.

Ask doctor before use if you have

- persistent chronic cough such as occurs with smoking, asthma, or emphysema
- cough accompanied by excessive phlegm (mucus)

Stop use and ask a doctor if

- 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.
- sore mouth does not improve in 7 days
- irritation, pain, or redness persists or worsens

Keep out of reach of children.

Directions

- adults and children 6 years and older: dissolve 2 drops (one at a time) slowly in the mouth. Repeat every 2 hours as needed or as directed by a doctor
- children under 6 years: ask a doctor

Other Information

Store in a dry place

Inactive Ingredients

color (caramel), extract of a Ricola herb mixture (elder, horehound, hyssop, lemon balm, linden flowers, mallow, peppermint, sage, thyme, wild thyme), natural flavor, starch syrup, sugar



THE ORIGINAL NATURAL HERB COUGH DROPS

menthol lozenge

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:54305-175
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	4.8 mg

Inactive Ingredients

Ingredient Name	Strength
SUCROSE (UNII: C151H8M554)	
CARAMEL (UNII: T9D99G2B1R)	

Product Characteristics

Color	brown (NUT BROWN)	Score	no score
Shape	RECTANGLE	Size	16mm
Flavor		Imprint Code	;
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:54305-175-21	21 in 1 BAG; Type 0: Not a Combination Product	01/01/1942	
2	NDC:54305-175-26	26 in 1 BAG; Type 0: Not a Combination Product	01/01/1942	12/29/2017
3	NDC:54305-175-93	130 in 1 BAG; Type 0: Not a Combination Product	01/01/1942	12/29/2017
4	NDC:54305-175-50	50 in 1 BAG; Type 0: Not a Combination Product	01/01/1942	
5	NDC:54305-175-27	27 in 1 BAG; Type 0: Not a Combination Product	01/01/1942	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	01/01/1942	

Labeler - Ricola Ag (480227248)

Establishment

Name	Address	ID/FEI	Business Operations
Ricola Ag		485393768	manufacture(54305-175)