COOL RELIEF ORAL ANESTHETIC- menthol lozenge Ricola USA Inc.

DUAL ACTION GLACIER MINT SUPPRESSANT ORAL ANESTHETIC

Drug Facts

Purpose

Cough suppressant, Oral anesthetic

Active Ingredient (in each drop)

Menthol, 15.3 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.

Keep out of reach of children.

Directions

- adults and children 6 years and older: dissolve 1 drop 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

protect from heat and moisture

Inactive Ingredients

extracts of peppermint and a Ricola herb mixture (elder, horehound, hyssop, lemon balm, linden flowers, mallow, peppermint, sage, thyme, wild thyme), glycerin, invert



COOL RELIEF ORAL ANESTHETIC

menthol lozenge

B			
Prodi	CT	Inform	ation
I I Out			ation

Product Type HUMAN OTC DRUG Item Code (Source) NDC:63667-153

Route of Administration ORAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength

MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)MENTHOL15.3 mg

Inactive Ingredients

Ingredient Name	Strenath

SUCROSE (UNII: C151H8M554)

Product Characteristics

Color	green	Score	no score
Shape	OVAL	Size	24mm
Flavor	MENTHOL (Icy Menthol)	Imprint Code	R
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:63667-153- 19	19 in 1 BAG; Type 0: Not a Combination Product	06/01/2018	
2	NDC:63667-153- 24	24 in 1 BAG; Type 0: Not a Combination Product	06/01/2018	
3	NDC:63667-153- 45	45 in 1 BAG; Type 0: Not a Combination Product	06/01/2018	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M022	06/01/2018	

Labeler - Ricola USA Inc. (177265261)

Establishment

Establishment			
Name	Address	ID/FEI	Business Operations
Ricola Ag		485393768	manufacture(63667-153)

Revised: 12/2024 Ricola USA Inc.