RICOLA MAX NASAL CARE COOL MENTHOL- menthol lozenge Ricola USA 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.

RICOLA MAX NASAL CARE COOL MENTHOL

Drug Facts

Purpose

Oral anesthetic

Active Ingredient (in each drop)

Menthol, 15.3 mg

Uses

temporarily relieves occasional minor irritation and pain associated with:

- sore mouth
- sore throat

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
- do not bite or chew

Other Information

Store in a dry place

Inactive Ingredients

extract of lemon balm and the Ricola herb mixture (elder, horehound, hyssop, lemon balm, linden flowers, mallow, peppermint, sage, thyme, wild thyme), colors (carrot, spirulina), flavors (lemon-thyme, peppermint), starch syrup, sugar



RICOLA MAX NASAL CARE COOL MENTHOL menthol lozenge

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:63667-206
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	Basis of Strength	Strength
MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	15.3 mg

Inactive Ingredients		
Ingredient Name	Strength	
SUCROSE (UNII: C151H8M554)		

Product Characteristics			
Color	green	Score	no score
Shape	OVAL	Size	24mm
Flavor	MENTHOL	Imprint Code	R
Contains			

P	Packaging			
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:63667-206- 34	34 in 1 BAG; Type 0: Not a Combination Product	03/01/2022	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part356	03/01/2022	

Labeler - Ricola USA Inc. (177265261)

Establishment				
Name	Address	ID/FEI	Business Operations	
Ricola Ag		485393768	manufacture(63667-206)	

Revised: 1/2023 Ricola USA Inc.