

COOL RELIEF ORAL ANESTHETIC- 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.

DUAL ACTION GLACIER MINT SUPPRESSANT ORAL ANESTHETIC

Drug Facts

Purpose

Cough suppressant, Oral anesthetic

Active Ingredient (in each drop)

Menthol, 8.3 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 sugar (fructose/dextrose), natural flavor, starch syrup, sugar

Sore throat • Oral Anesthetic Drops
Icy Menthol
Cools & Relieves

Purposes

Sore throat warnings

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Keep out of reach of children.

Uses temporarily relieves occasional minor irritation and

- sore mouth

- sore throat

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- directed by a doctor.
- children under 6 years: ask a doctor
- do not bite or chew

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Other Information

Other Information protect from heat and moisture

inactive ingredients: extract of lemon balm and the Riccia herb mixture (elder, horehound, hyssop, lemon balm, linden flowers, mallow, peppermint, sage, thyme, wild thyme), colors (carrot, spirulina), flavors (lemon-thyme, peppermint), starch syrup, sucralose.

9012327 US
Exp. Date:

Batch:

NEW

MAX STRENGTH

Ricola

COOL RELIEF

Sore Throat • Oral Anesthetic Drops

Icy Menthol

From Switzerland

19 DROPS

Quicola

Ricola Cool Relief sore throat drops provide relief for severe sore throats and cools your nasal passages so you can keep going. With our unique blend of 10 Swiss alpine herbs, and the power of menthol, Ricola Cool Relief sore throat drops give you effective relief when you need it most.

Riccola have been used around the world for centuries. For over 80 years, Riccola has been making pleasant tasting natural herbal products. Riccola is nature's way of soothing sore throats.

For questions or comments, contact:

Manufacturers

Nicola



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menthol lozenge

Product Information

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)	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 (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 final	part341	06/01/2018	

Labeler - Ricola USA Inc. (177265261)

Establishment

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

