

DUAL ACTION GLACIER MINT COUGH SUPPRESSANT 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.

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 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

DUAL ACTION

Cough Suppressant • Oral Anesthetic Drops

Glacier Mint®

Soothes Cough

Relieves Sore Throat

Drug Facts

Active ingredient (in each drop) Menthol, 6.3 mg, Cough suppressant, Oral anesthetic

Purposes

Uses Temporarily relieves:
• cough due to a cold or related ailments • 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 7 days, is accompanied by fever, or is accompanied by headache, rash, swelling, nausea, or vomiting, consult a doctor promptly. These may be serious.

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: • 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 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

protected from heat and moisture

Inactive ingredients: extracts of peppermint and a local herb mixture (elder, rosemary, thyme, lemon balm, daisy flowers, yarrow, peppermint, sage, lemon balm, dried lavender sugar (Sucrose Octaose), natural flavor, starch syrup, sugar

9012223 US

Exp. Date:

Batch:



Ricola

DUAL ACTION

Cough Suppressant • Oral Anesthetic Drops

SOOTHES  SORE THROAT

RELIEVES SORE THROAT



Glacier Mint®
From Switzerland
19 DROPS

Product shown larger than actual size



Ricola

Ricola Dual Action drops provide naturally effective relief for both your cough and sore throat. Our unique blend of ten natural Swiss alpine herbs, natural menthol and soothing syrup center, combine to give you fast, safe relief you can trust.

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

For questions or comments, contact:
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Product of Switzerland.

Ricola
Naturally Effective®

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DUAL ACTION GLACIER MINT COUGH SUPPRESSANT ORAL ANESTHETIC

menthol lozenge

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:63667-603
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	8.3 mg

Inactive Ingredients

Ingredient Name	Strength
SUCROSE (UNII: C151H8M554)	
GLYCERIN (UNII: PDC6A3C0OX)	

Product Characteristics

Color	yellow	Score	no score
Shape	OVAL	Size	24mm
Flavor	MINT	Imprint Code	R
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:63667-603-19	19 in 1 BAG; Type 0: Not a Combination Product	01/01/2016	
2	NDC:63667-603-26	26 in 1 BAG; Type 0: Not a Combination Product	01/01/2016	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	01/01/2016	

Labeler - Ricola USA Inc. (177265261)

Establishment

Name	Address	ID/FEI	Business Operations
Ricola Ag		485393768	manufacture(63667-603)

