

COOL RELIEF ORAL ANESTHETIC- 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.

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

Bulk Label

Ricola AG Baselstrasse 31
CH-4242-Laufen
Schweiz/Switzerland

Vertrieb durch:

Ricola

6002307

COOL RELIEF ICY MENTHOL

.. Big-Bags at 800 Kg



Charge/
Lot/Lot

18150947

12.08.2018

Abzupacken bis

376107000068254991

SSCC

Netto Gewicht / Net weight / Poids net

758 KG

Füllgewicht / Filling weight /

Poids de remplissage

800 KG

Gewicht Bag/ Weight bag/ Poids bag

805 KG

Palettengewicht / Pallet weight /

Poids de palette

823 KG

Start-Zeit / Start time / temps du décollage

12.04.2018 05:04

Ende-Zeit / End time / temps du fin

12.04.2018 07:12

Hiermit bestätige ich, dass die Angaben korrekt sind und die Zuordnung zur Palettenidentifikation korrekt erfolgte.

Herewith I confirm the correction of the information and the correct allocation to the pallet identification.

Je confirme par la présente que les informations et que l'attribution de l'identification des palettes sont corrects.

Palettennummer / Number of
pallet / Numéro de palette

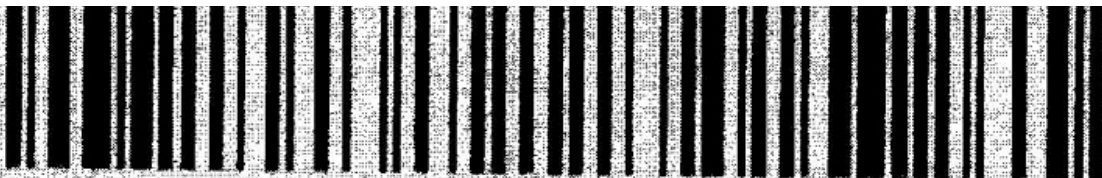
001

Mitarbeiter

Employee Employé

W-K7





(00)376107000068254991

menthol lozenge

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:54305-153
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:54305-153-19	19 in 1 BAG; Type 0: Not a Combination Product	06/01/2018	
2	NDC:54305-153-24	24 in 1 BAG; Type 0: Not a Combination Product	06/01/2018	
3	NDC:54305-153-45	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 Ag (480227248)

Establishment

Name	Address	ID/FEI	Business Operations
Ricola Ag		485393768	manufacture(54305-153)

