

THROAT BALM CARAMEL PECTIN- pectin 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 Throat Balm Caramel Pectin

Active ingredient (in two drops)

Pectin 7.6 mg

Purpose

Oral demulcent

Uses temporarily relieves:

occasional minor irritation and pain associated with

- sore mouth
- sore throat

Warnings

Do not use

- in children under 6 years of age unless directed by a doctor.

Stop use and ask a doctor if

- sore throat is severe, persists for more than 2 days, or is accompanied by fever, headache, rash, nausea, or vomiting.
- sore mouth symptoms do not improve in 7 days.

Keep out of reach of children.

Directions

- adults and children 6 years and older: dissolve 2 drops (one at a time) slowly in the mouth. Do not bite or chew. 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: Caramel sugar syrup; cocoa butter; emulsifier (sunflower lecithin), extracts of bee balm, Ricola herb mixture (elder, horehound, hyssop, lemon balm, linden flowers, mallow, peppermint, sage, thyme, wild thyme) and rooibos; glucose syrup; glucose-fructose syrup; honey; humectant (glycerine); natural flavoring (caramel, echinacea purpurea fresh plant pressed juice powder, honey, menthol, peppermint, vanilla); salt; sugar



ARLÉNSIS <small>ARLÉNSIS</small> Telephone +41 44 518 03 81 Material number 9014779 Material short text BT HERMELECH 34cl US, US-Throat Balm 34cl Film Recipe number 365 Project number 9001 Print Process Gravure printing Printing works RATTPACK File name BT-HERMELECH 34cl US 9014779 edit.ai Date 17.11.2022 Copy amendment naqa.rich@arlensis.com		Colors Euroscala cyan magenta yellow black Non-printing Cutter Info Printing inks number: 7 Font sizes other text minimum (x-size = 1.35 mm)	Corporate colors PANTONE 7734 C Flavor colors PANTONE 7698 C PANTONE 144 C
Design number 7			

THROAT BALM CARAMEL PECTIN

pectin lozenge

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:63667-301
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
PECTIN (UNII: 89NA02M4RX) (PECTIN - UNII:89NA02M4RX)	PECTIN	3.8 mg

Inactive Ingredients

Ingredient Name	Strength
SUCROSE CARAMEL (UNII: D8GMM4517Q)	

Product Characteristics

Color	brown	Score	no score
Shape	OVAL	Size	24mm
Flavor	CARAMEL	Imprint Code	R
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:63667-301-34	34 in 1 BAG; Type 0: Not a Combination Product	11/01/2022	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part356	11/01/2022	

Labeler - Ricola USA Inc. (177265261)

Establishment

Name	Address	ID/FEI	Business Operations
Ricola Ag		485393768	manufacture(63667-301)

Revised: 1/2023

Ricola USA Inc.