

**PREVASIL ULTRA CARE LIP BALM- camphor, thymol stick
Bolm, 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.

Active ingredients

Camphor- 3.10% Thymol 0.13%

Purpose

External Analgesic

Warnings

For external use only

Do not use if you are allergic or sensitive to any ingredient in this product

When using this product

- apply only to the affected areas
- do not use in or near the eyes
- avoid applying directly inside the mouth
- do not share this product with anyone, as this may spread infection

Uses

- helps treat and provide temporary relief from symptoms of cold sores/fever blisters
- temporarily protects and helps relieve chapped or cracked lips

Stop use and ask a doctor

Stop use and ask a doctor if condition worsens or does not improve within 7 days

Keep out of reach of children

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away. CHOKING HAZARD. Has removable cap.

Directions

- for cracking or dryness, continue to cover lips until absorbed
- use daily on the lips as needed during periods of high stress, sickness or fatigue, or apply liberally to the affected area within the first hour of an emerging cold sore
- rub in gently but completely
- for cold sores/fever blisters, reapply liberally as the cooling effect wears off and continue reapplying throughout the following 8 hours, or until symptoms subside

Storage

- Keep away from heat. Do not freeze. Store at room temperature 20^o-25^oC (68^o-77^oF)

Inactive Ingredients

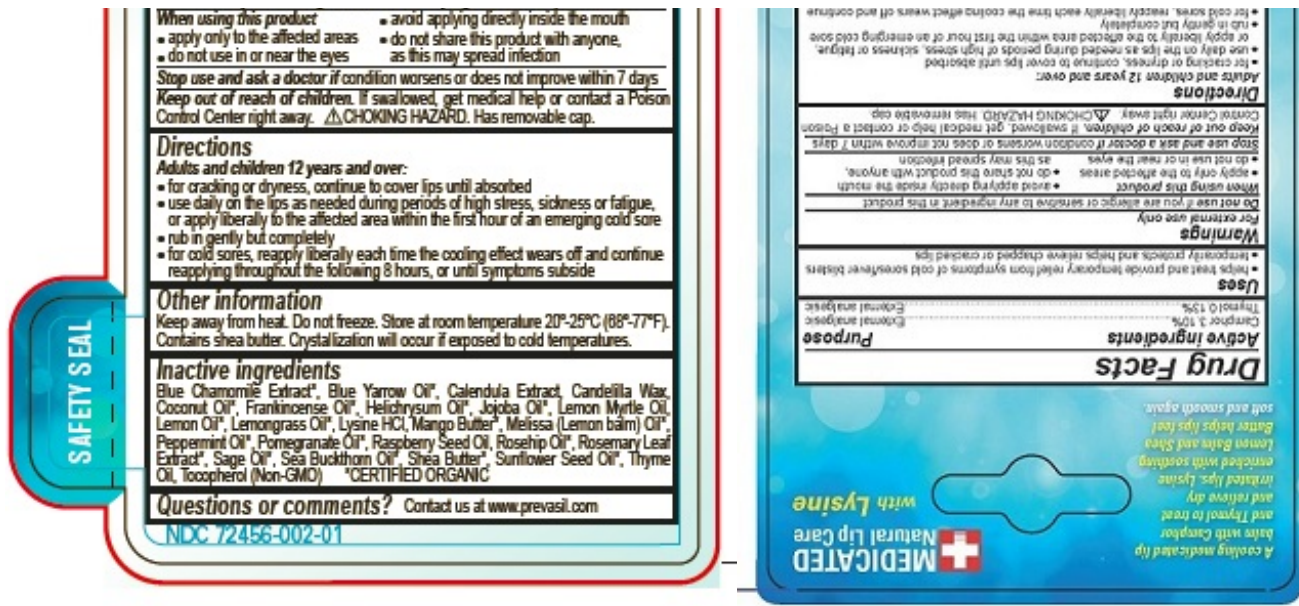
Blue Chamomile Extract*, Blue Yarrow Oil*, Calendula Extract, Candelilla Wax, Coconut Oil*, Frankincense Oil*, Helichrysum Oil*, Jojoba Oil*, Lemon Myrtle Oil, Lemon Oil*, Lemongrass Oil*, Lysine HCl, Mango Butter*, Melissa (Lemon balm) Oil*, Peppermint Oil*, Pomegranate Oil*, Raspberry Seed Oil, Rosehip Oil*, Rosemary Leaf Extract*, Sage Oil*, Sea Buckthorn Oil*, Shea Butter*, Sunflower Seed Oil*, Thyme Oil, Tocopherol (Non-GMO) *CERTIFIED ORGANIC

Questions or comments?

Contact us at www.prevasil.com

Product Label





PREVASIL ULTRA CARE LIP BALM

camphor,thymol stick

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:72456-002
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
CAMPHOR (SYNTHETIC) (UNII: 5TJD82A1ET) (CAMPHOR (SYNTHETIC) - UNII:5TJD82A1ET)	CAMPHOR (SYNTHETIC)	31 mg in 1 g
THYMOL (UNII: 3J50XA376E) (THYMOL - UNII:3J50XA376E)	THYMOL	1.3 mg in 1 g

Inactive Ingredients

Ingredient Name	Strength
CHAMOMILE (UNII: FGL3685T2X)	
ACHILLEA MILLEFOLIUM OIL (UNII: 97P5D0WG43)	
CALENDULA OFFICINALIS FLOWER (UNII: P0M7O4Y7YD)	
CANDELILLA WAX (UNII: WL0328HX19)	
COCONUT OIL (UNII: Q9L0O73W7L)	
FRANKINCENSE OIL (UNII: 67ZYA5T02K)	
HELICHRYSUM ITALICUM FLOWER OIL (UNII: O97ZV7726K)	
JOJOBA OIL (UNII: 724GKU717M)	
BACKHOUSIA CITRIODORA LEAF OIL (UNII: 2UQQ0PI06P)	
LEMON OIL (UNII: I9GRO824LL)	
EAST INDIAN LEMONGRASS OIL (UNII: UP0M8M3VZW)	
LYSINE HYDROCHLORIDE (UNII: JNJ23Q2COM)	
MANGIFERA INDICA SEED BUTTER (UNII: 4OXD9M35X2)	
MELISSA OFFICINALIS LEAF OIL (UNII: PTP6R7263M)	
PEPPERMINT OIL (UNII: AV092KU4JH)	

POMEGRANATE SEED OIL (UNII: 0UI45XV0T6)	
RASPBERRY SEED OIL (UNII: 9S8867952A)	
ROSA MOSCHATA OIL (UNII: J99W255AWF)	
ROSEMARY (UNII: IJ67X351P9)	
SAGE OIL (UNII: U27K0H1H2O)	
HIPPOPHAE RHAMNOIDES SEED OIL (UNII: T53SBG6741)	
SHEA BUTTER (UNII: K49155WL9Y)	
SUNFLOWER OIL (UNII: 3W1JG795Y)	
THYME OIL (UNII: 2UK410MY6B)	
TOCOPHEROL (UNII: R0ZB2556P8)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:72456-002-01	4.25 g in 1 TUBE; Type 0: Not a Combination Product	05/01/2019	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	05/01/2019	

Labeler - Bolm, Inc. (081276782)

Establishment

Name	Address	ID/FEI	Business Operations
Raining Rose, Inc.		083819404	manufacture(72456-002)

Revised: 4/2019

Bolm, Inc.