

REAL TIME PAIN RELIEF VEGAN SELECT- menthol lotion
Cosmetic Specialty Labs, 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.

Real Time Pain Relief Cream Vegan Select

Active Ingredient

Menthol 1.25%

Purpose

Topical Analgesic

Uses

temporarily relieves minor pain associated with:

- arthritis
- simple backache
- muscle strains
- sprains
- bruises
- cramps

Warnings

for external use only

When using this product

- avoid contact with eyes or mucous membranes
- do not apply to wounds or damaged skin
- do not bandage tightly

Stop use and ask a doctor if

- condition worsens
- symptoms persist for more than 7 days or clear up and occur again within a few days
- redness is present
- irritation develops

If pregnant or breast-feeding,

ask a health professional before use

Keep out of reach of children

If swallowed, get medical help or contact a Poison Control Center right away.

Directions:

adults and children over 2 years:

- apply generously to affected area
- massage into painful area until thoroughly absorbed into skin
- repeat as necessary, but no more than 4 times daily

children 2 years or younger: ask a doctor

Inactive ingredients:

Aloe Barbadosis Leaf, Anthemis nobilis, Arnica Montana Flower Extract, Butylene Glycol, Calendula officinalis, Caprylyl Glycol, Capsicum Frutescens Fruit Extract, Carbomer, Centaurea cyanus, Cetearyl Alcohol, Cetyl Alcohol, Coriandrum Sativum (Coriander) Fruit Oil, Fragrance, Hamamelis Virginiana (Witch Hazel) Bark/Leaf/Twig Extract, Hypericum perforatum, Matricaria chamomilla, Methylsulfonylmethane, Phenoxyethanol, Purified Water, Rubus Idaeus (Raspberry) Seed Oil, Salix Alba (Willow) Bark Extract, SD Alcohol 40, Sorbitol, Tilia cordata, Triethanolamine.

Package Label, Principal Display Panel and Drug Facts



**VEGAN
SELECT**

With Raspberry Oil

**Provides Temporary Relief from:
Arthritis, Muscle Strains,
Sprains, Bruises, Cramps.**

Pain Relieving Cream

Net Wt. 12 Fl. Oz. / 355 mL

Drug Facts

Active Ingredient	Purpose
Menthol 1.25%.....	Topical analgesic

Uses temporarily relieves minor pain associated with:
■ arthritis ■ simple backache ■ muscle strains ■ sprains
■ bruises ■ cramps

Warnings for external use only

When using this product ■ use only as directed
■ avoid contact with eyes or mucous membranes
■ do not apply to wounds or damaged skin
■ do not bandage tightly

Stop use and ask a doctor if ■ condition worsens
■ symptoms persist for more than 7 days or clear up and occur again within a few days ■ redness is present ■ irritation develops

If pregnant or breast-feeding, ask a health professional before use.

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

Directions:

adults and children over 2 years: ■ apply generously to affected area ■ massage into painful area until thoroughly absorbed into skin ■ repeat as necessary, but no more than 4 times daily
children 2 years or younger: ask a doctor

Inactive ingredients Aloe Barbadosis Leaf, Anthemis nobilis, Arnica Montana Flower Extract, Butylene Glycol, Calendula officinalis, Caprylyl Glycol, Capsicum Frutescens Fruit Extract, Carbomer, Centaurea cyanus, Cetearyl Alcohol, Cetyl Alcohol, Coriandrum Sativum (Coriander) Fruit Oil, Fragrance, Hamamelis Virginiana (Witch Hazel) Bark/Leaf/Twig Extract, Hypericum perforatum, Matricaria chamomilla, Methylsulfonylmethane, Phenoxyethanol, Purified Water, Rubus Idaeus (Raspberry) Seed Oil, Salix Alba (Willow) Bark Extract, SD Alcohol 40, Sorbitol, Tilia cordata, Triethanolamine.

NDC #58133-555-12
Distributed by: RTPR LLC,
Edmond, OK 73003
www.RTPR.com



menthol lotion

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:58 133-555
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	1.25 g in 100 mL

Inactive Ingredients

Ingredient Name	Strength
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
ARNICA MONTANA FLOWER (UNII: OZ0E5Y15PZ)	
CAPSICUM FRUTESCENS WHOLE (UNII: 6XJX33L87P)	
ANTHEMIS ARVENSIS FLOWERING TOP (UNII: 851P1R9YK)	
BUTYLENE GLYCOL (UNII: 3XUS85K0RA)	
CARBOMER 940 (UNII: 4Q93RCW27E)	
CORIANDRUM SATIVUM WHOLE (UNII: 740M8BF6EF)	
WATER (UNII: 059QF0K00R)	
CALENDULA OFFICINALIS SEED OIL (UNII: 9JS8DS42SV)	
CENTAUREA CYANUS FLOWER (UNII: QZ239038YC)	
HYPERICUM PERFORATUM (UNII: XK4IUX8MNB)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	
HAMAMELIS VIRGINIANA BARK (UNII: IH3063S9MY)	
SALIX ALBA BARK (UNII: 205MXS71H7)	
TERT-BUTYL ALCOHOL (UNII: MD83SFE959)	
MATRICARIA CHAMOMILLA FLOWERING TOP OIL (UNII: SA8AR2W4ER)	
3,4-METHYLENEDIOXYBENZYL METHYLSULFONE (UNII: 4W601CSX19)	
CETYL ALCOHOL (UNII: 936JST6JCN)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
SORBITOL (UNII: 506T60A25R)	
TILIA CORDATA FLOWER (UNII: CFN6G1F6YK)	
TRIETHANOLAMINE TRIS(DIHYDROGEN PHOSPHATE) (UNII: 36YHT392ID)	
RUBUS IDAEUS FRUIT VOLATILE OIL (UNII: 276X2YNL0K)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:58 133-555-03	90 mL in 1 TUBE, WITH APPLICATOR; Type 0: Not a Combination Product	01/30/2013	
2	NDC:58 133-555-12	355 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	01/30/2013	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	01/30/2013	

Labeler - Cosmetic Specialty Labs, Inc. (032973000)

Registrant - Cosmetic Specialty Labs, Inc. (032973000)

Establishment

Name	Address	ID/FEI	Business Operations
Cosmetic Specialty Labs, Inc.		032973000	manufacture(58133-555)

Revised: 1/2018

Cosmetic Specialty Labs, Inc.