REAL TIME PAIN RELIEF FOOT CREAM TOPICAL ANALGESIC- menthol 1.5% cream
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 Foot Cream

ACTIVE INGREDIENT

Menthol 1.5%

PURPOSE

Topical analgesic

KEEP OUT OF REACH OF CHILDREN

If swallowed, get medical help or contact a poison control center right away.

USES

Temporarily relieves minor pain associated with

- arthritis
- muscle strains
- sprains
- bruises
- cramps

WARNINGS

for external use only

When using this product

- use only as directed
- do not bandage tightly or use with heating pad
- avoid contact with eyes or mucus membranes
- do not apply to wounds or damaged skin

Stop using 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

DIRECTIONS

adults and children over 2 years

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

Children 2 years or younger:ask a doctor

INACTIVE INGREDIENTS

Allantoin, Aloe barbadensis Leaf Juice, Anthemis nobilis (Roman Chamomile), Ascorbic Acid, Butylene Glycol, Calendula officianlis (Marigold), Caprylyl Glycol, Centaurea cyanus (Cornflower), Cetearyl Alcohol, Cetyl Alcohol, Coriandrum sativum (Coriander) Fruit Oil, Emu Oil, Eucalyptus globulus Leaf Oil, Hydrogenated Vegetable Oil, Hypericum perforatum (St. John's Wort), Lactic Acid, Lanolin, Matricaria chamomilla (Chamomile), Melaleuca alternifolia (Tea Tree) Leaf Oil, Paraffin, Petrolatum, Phenoxyethanol, Polysorbate-20, Polysorbate-60, Purified Water, Retinyl Palmitate, Salix alba (Willow) Bark Extract, SD Alcohol 40, Sodium Borate, Sorbitan Sesquioleate, Stearyl Alcohol, Tilia sylvestris (Lime Tree), Tocopheryl Acetate.

PRINCIPAL DISPLAY PANEL and DRUG FACTS

REAL TIME PAIN RELIEF FOOT CREAM TOPICAL ANALGESIC

menthol 1.5% cream

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:58133-900
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	1.5 g in 100 g

Inactive Ingredients	
Ingredient Name	**Strength**
TILIA X EUROPAEA FLOWER (UNII: NHV2K1OUDH)	
ALPHA-TOCOPHERYLOXYACETIC ACID (UNII: JW7FJR3ZLY)	
ASCORBIC ACID (UNII: PQ6CK8PD0R)	
BUTYLENE GLYCOL (UNII: 3XUS85K0RA)	

MATRICARIA CHAMOMILLA FLOWERING TOP OIL (UNII: SA8AR2W4ER)	
POLYSORBATE 60 (UNII: CAL22UVI4M)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
ALLANTOIN (UNII: 344S277G0Z)	
CHAMOMILE FLOWER OIL (UNII: 60F80Z61A9)	
LACTIC ACID (UNII: 33X04XA5AT)	
CALENDULA OFFICINALIS FLOWER (UNII: P0M7O4Y7YD)	
LANOLIN (UNII: 7EV65EAW6H)	
MELALEUCA ALTERNIFOLIA LEAF (UNII: G43C57162K)	
CENTAUREA CYANUS FLOWER (UNII: QZ239038YC)	
CETYL ALCOHOL (UNII: 936JST6JCN)	
CORIANDER OIL (UNII: 7626GC95E5)	
POLYSORBATE 20 (UNII: 7T1F30V5YH)	
EMU OIL (UNII: 344821WD61)	
WATER (UNII: 059QF0KO0R)	
SALIX ALBA BARK (UNII: 205MXS71H7)	
PARAFFIN (UNII: I9O0E3H2ZE)	
PETROLATUM (UNII: 4T6H12BN9U)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
EUCALYPTUS GLOBULUS LEAF (UNII: S546YLW6E6)	
HYDROGENATED COTTONSEED OIL (UNII: Z82Y2C65EA)	
HYPERICUM PERFORATUM (UNII: XK4IUX8MNB)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
RETINYL PROPIONATE (UNII: 32JK994WMC)	
.ALPHA.-ISOBUTYLPHENETHYL ALCOHOL (UNII: 2SBL0E1I0N)	
SODIUM BORATE (UNII: 91MBZ8H3QO)	
SORBITAN SESQUIOLEATE (UNII: 0W8RRI5W5A)	
ISOSTEARYL ALCOHOL (UNII: Q613OCQ44Y)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:58133-900-04	125 g in 1 JAR; Type 0: Not a Combination Product	01/31/2014	
2	NDC:58133-900-14	40 g in 1 JAR; Type 0: Not a Combination Product	01/31/2014	
3	NDC:58133-900-08	227 g in 1 JAR; Type 0: Not a Combination Product	01/31/2014	
4	NDC:58133-900-16	453 g in 1 JAR; Type 0: Not a Combination Product	01/31/2014	

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(58133-900)

Revised: 1/2018

Cosmetic Specialty labs, Inc.