

REAL TIME PAIN RELIEF CREAM- 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

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

- 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:

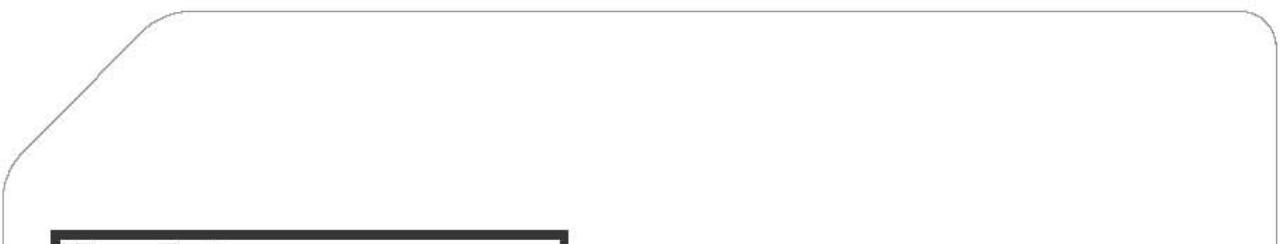
- apply generously to affected area
- massage into painful area until thoroughly absorbed into skin
- repeat as necessary, but no more than 4 times daily

children 2 years or younger: ask a doctor

Inactive ingredients:

Aloe Barbadosensis Leaf, Anthemis nobilis Extract, Arnica Montana Flower Extract, Butylene Glycol, Calendula officianlis Extract, Caprylyl Glycol, Capsicum Frutescens Fruit, Carbomer, Centaurea cyanus Extract, Cetearyl Alcohol, Cetyl Alcohol, Coriandrum Sativum (Coriander) Fruit Oil, Diazolidinyl Urea, Emu Oil, Fragrance, Glucosamine HCl, Hamamelis Virginiana (Witch Hazel) Bark/Leaf/Twig Extract, Hypericum perforatum Extract, Matricaria chamomilla Extract, Methylsulfonylmethane, Phenoxyethanol, Purified Water, Salix Alba (Willow) Bark Extract, SD Alcohol 40, Sodium Chondroitin Sulfate, Sorbitol, Tilia cordata Extract, Triethanolamine.

Package Label, Principal Display Panel and Drug Facts



Drug Facts

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

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

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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

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 ■ 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.

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 medical help or contact a Poison Control Center right
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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 Barbadosensis Leaf, Anthemis
 nobilis Extract, Arnica Montana Flower Extract, Butylene
 Glycol, Calendula officinalis Extract, Caprylyl Glycol,
 Capsicum Frutescens Fruit, Carbomer, Centaurea
 cyanus Extract, Cetearyl Alcohol, Cetyl Alcohol,
 Coriandrum Sativum (Coriander) Fruit Oil, Diazoldinyl
 Urea, Emu Oil, Fragrance, Glucosamine HCl, Hamamelis
 Virginiana (Witch Hazel) Bark/Leaf/Twig Extract,
 Hypericum perforatum Extract, Matricaria chamomilla
 Extract, Methylsulfonylmethane, Phenoxethanol,
 Purified Water, Salix Alba (Willow) Bark Extract, SD
 Alcohol 40, Sodium Chondroitin Sulfate, Sorbitol, Tilia
 cordata Extract, Triethanolamine.

REAL TIME PAIN RELIEF CREAM

menthol lotion

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:58 133-600
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: 851IP1R9YK)	
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)	
SODIUM CHONDROITIN SULFATE (PORCINE; 5500 MW) (UNII: H5BJH23Z9A)	
HYPERICUM PERFORATUM (UNII: XK4IUX8MNB)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
EMU OIL (UNII: 344821WD61)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	
DIAZOLIDINYL UREA (UNII: H5RIZ3MPW4)	
GLUCOSAMINE HYDROCHLORIDE (UNII: 750W5330FY)	
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)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:58133-600-15	45 mL in 1 TUBE; Type 0: Not a Combination Product	01/30/2013	
2	NDC:58133-600-07	210 mL in 1 TUBE; Type 0: Not a Combination Product	01/30/2013	
3	NDC:58133-600-04	120 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	01/30/2013	
4	NDC:58133-600-12	354 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	01/30/2013	
5	NDC:58133-600-16	473 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	01/30/2013	

6	NDC:58 133-600-40	120 mL in 1 TUBE; Type 0: Not a Combination Product	01/30/2013	
7	NDC:58 133-600-33	98 mL in 1 TUBE; 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(58 133-600)

Revised: 12/2017

Cosmetic Specialty Labs, Inc.