

**REAL TIME PAIN RELIEF SPORTS CREAM TOPICAL ANALGESIC- menthol 0.5% 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.*

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**Real Time Pain Relief Sports Cream**

**ACTIVE INGREDIENT**

Menthol 0.5%

**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
- simple backache
- muscle strains
- sprains
- bruises

**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 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 thoroughly absorbed into skin
- repeat as necessary, but no more than 4 times daily

children 2 years or younger: ask a doctor

**children 12 years or younger**

ask a doctor

**INACTIVE INGREDIENTS**

Aloe Barbadensis Leaf Juice, Anthemis nobilis (Roman Chamomile), Arnica Montana Flower Extract, Butylene Glycol, Calendula officianlis (Marigold), Caprylyl Glycol, Carbomer, Centaurea cyanus (Cornflower), Cetearyl Alcohol, Cetyl Alcohol, Chamomilla Recutita (Matricaria Chamomilla), Coriandrum Sativum (Coriander) Fruit Oil, Curcuma Longa (Turmeric) Extract, Cupressus sempervirens (Cypress) Fruit Extract, Emu Oil, Fragrance, Gaultheria procumbens (Wintergreen) Oil, Glycerin, Hamamelis Virginiana (Witch Hazel) Bark/Leaf/Twig Extract, Helichrysum Italicum Flower, Hypericum perforatum (St. John’s Wort), Jasminum Officianale (Jasmine) Flower Extract, Lavendula Angustifolia (Lavender) Oil, Magnesium Chloride, Methylsulfonylmethane, Myristica Fragrans (Nutmeg) Extract, Origanum Majorana (Marjoram) Leaf Extract, Phenoxyethanol, Purified Water, Rosmarinus Officinalis (Rosemary) Leaf Extract, Salix Alba (Willow) Bark Extract, SD Alcohol 40, Sorbitol, Tetrasodium EDTA, Tilia cordata (Lime Tree), Triethanolamine.

**PRINCIPAL DISPLAY PANEL**



**Drug Facts** continued

Other ingredients: Aloe Barbadosensis Leaf Juice, Anthemis nobilis (Roman Chamomile), Arnica Montana Flower Extract, Butylane Glycol, Calendula officinalis (Marigold), Caprylyl Glycol, Carbomer, Centaurea cyanus (Cornflower), Cetyl Alcohol, Cetyl Alcohol, Chamomilla Recutita (Matricaria Chamomilla), Coriandrum Sativum (Coriander) Fruit Oil, Curcuma Longa (Turmeric) Extract, Cupressus sempervirens (Cypress) Fruit Extract, Emu Oil, Fragrance, Gaultheria procumbens (Wintergreen) Oil, Glycerin, Hamamelis Virginiana (Witch Hazel) Bark/Leaf/Twig Extract, Helichrysum Italicum Flower, Hypericum perforatum (St. John's Wort), Jasminum Officinale (Jasmine) Flower Extract, Lavandula Angustifolia (Lavender) Oil, Magnesium Chloride, Methylsulfonylmethane, Myristica Fragrans (Nutmeg) Extract, Origanum Majorana (Marjoram) Leaf Extract, Phenoxethanol, Purified Water, Rosmarinus Officinalis (Rosemary) Leaf Extract, Salix Alba (Willow) Bark Extract, SD Alcohol 40, Sorbitol, Tetrasodium EDTA, Tilia cordata (Lime Tree), Triethanolamine.

**Drug Facts**

Active Ingredient	Purpose
Menthol 0.5%.....	Topical analgesic

Use 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

**REAL TIME PAIN RELIEF SPORTS CREAM TOPICAL ANALGESIC**

menthol 0.5% lotion

**Product Information**

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:58 133-700
<b>Route of Administration</b>	TOPICAL		

**Active Ingredient/Active Moiety**

<b>Ingredient Name</b>	<b>Basis of Strength</b>	<b>Strength</b>
MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	0.5 g in 100 mL

**Inactive Ingredients**

<b>Ingredient Name</b>	<b>Strength</b>
ALOE VERA LEAF (UNII: ZY8 1Z83H0 X)	
CHAMAEMELUM NOBILE FLOWER (UNII: O2T154T6OG)	
ARNICA MONTANA FLOWER (UNII: OZ0E5Y15PZ)	
CALENDULA OFFICINALIS FLOWER (UNII: P0M7O4Y7YD)	
CARBOMER 934 (UNII: Z135WT9208)	
CENTAUREA CYANUS FLOWER (UNII: QZ239038 YC)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	
CETYL ALCOHOL (UNII: 936JST6JCN)	
CORIANDER OIL (UNII: 7626GC95E5)	
MAGNESIUM CHLORIDE (UNII: 02F3473H9O)	
EMU OIL (UNII: 344821WD61)	
GLUCOSAMINE HYDROCHLORIDE (UNII: 750W5330FY)	
HAMAMELIS VIRGINIANA TOP (UNII: UDA30A2JJY)	
WATER (UNII: 059QF0KO0R)	
SALIX ALBA BARK (UNII: 205MXS71H7)	
SORBITOL (UNII: 506T60A25R)	
TILIA X EUROPAEA FLOWER (UNII: NHV2K10UDH)	
MYRISTICA FRAGRANS WHOLE (UNII: MF7T8BM40A)	
TETRASODIUM DIETHYLENETRIAMINEPENTAMETHYLENPHOSPHONATE (UNII: E6DVO371LC)	
BUTYLENE GLYCOL (UNII: 3XUS85K0RA)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
CURCUMA LONGA LEAF (UNII: H2HC4RY52C)	
DIMETHYL SULFONE (UNII: 9H4PO4Z4FT)	
2-(DIPROPYLAMINO)ETHANOL (UNII: 0916206V9S)	
HELICHRYSUM ITALICUM FLOWER (UNII: P62Y550X24)	
JASMINUM OFFICINALE FLOWER (UNII: 0Q8K841432)	
LAVENDER OIL (UNII: ZBP1YXW0H8)	
ORIGANUM MAJORANA (UNII: R40XM3HU5X)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
ROSMARINUS OFFICINALIS FLOWERING TOP OIL (UNII: OXN0D3N28L)	
TRIETHANOLAMINE TRIS(DIHYDROGEN PHOSPHATE) (UNII: 36YHT392ID)	
HYPERICUM PERFORATUM (UNII: XK4IUX8MNB)	
ANTHEMIS ARVENSIS FLOWERING TOP (UNII: 851IP1R9YK)	
CUPRESSUS SEMPERVIRENS LEAF OIL (UNII: M7QUY89S4O)	
GAULTHERIA PROCUMBENS LEAF (UNII: 2125M16OWN)	
GLYCERIN (UNII: PDC6A3C0OX)	

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:58 133-700-04	120 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	01/31/2014	
2	NDC:58 133-700-12	345 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	01/31/2014	
3	NDC:58 133-700-40	120 mL in 1 TUBE; Type 0: Not a Combination Product	01/31/2014	
4	NDC:58 133-700-15	45 mL in 1 TUBE; 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(58 133-700)

Revised: 1/2018

Cosmetic Specialty labs, Inc.