

MARATHON PAIN RELIEF TOPICAL ANALGESIC- menthol 3.0% 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.

ACTIVE INGREDIENT

Menthol 3.0%

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
- 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 12 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 12 years or younger

ask a doctor

INACTIVE INGREDIENTS

Aloe Barbadensis Leaf, Anthemis Nobilis Extract, Arnica Montana Flower Extract, Blue 1, Butylene Glycol, Calendula Officinalis Extract, Capsicum rutescens Fruit, Carbomer, Centaurea Cyanus Extract, Cetearyl Alcohol, Coriandrum Sativum (Coriander) Fruit Oil, Emu Oil, Fragrance, Hamamelis Virginiana (Witch Hazel) Bark/Leaf/Twig Extract, Hypericum Perforatum Extract, Matricaria Chamomilla Extract, Methylsulfonylmethane, Purified Water, Salix Alba (Willow) Bark Extract, SD Alcohol 40, Sorbitol, Tetrasodium EDTA, Tilia Sylvestris Extract, Triethanolamine.

PRINCIPAL DISPLAY PANEL



Goes On in Seconds - Works in Minutes - Lasts for Hours

PAIN RELIEF

Rub it Where it Hurts™

Sore Muscles & Joints | Arthritis | Sprains & Strains | Simple Back Ache

Topical Analgesic

Net Wt. 4 Oz. / 113 g.



Drug Facts

Active Ingredient	Purpose
Menthol 3.0%	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 ■ do not bandage tightly or use with heating pad ■ avoid contact with eyes or mucous membranes ■ do not apply to wounds or damaged skin

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 12 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 12 years or younger: ask a doctor

Inactive ingredients Aloe Barbadosensis Leaf, Anthemis Nobilis Extract, Arnica Montana Flower Extract, Blue 1, Butylene Glycol, Calendula Officinalis Extract, Capsicum Frutescens Fruit, Carbomer, Centaurea Cyanus Extract, Cetearyl Alcohol, Coriandrum Sativum (Coriander) Fruit Oil, Emu Oil, Fragrance, Hamamelis Virginiana (Witch Hazel) Bark/Leaf/Twig Extract, Hypericum Perforatum Extract, Matricaria Chamomilla Extract, Methylsulfonylmethane, Purified Water, Salix Alba (Willow) Bark Extract, SD Alcohol 40, Sorbitol, Tetrasodium EDTA, Tilia Sylvestris Extract, Triethanolamine.

Manufactured for:

Marathon Pain Relief

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MARATHON PAIN RELIEF TOPICAL ANALGESIC

menthol 3.0% lotion

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:58133-001
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
menthol (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	menthol	3 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
CHAMAEMELUM NOBILE FLOWER (UNII: O2T154T6OG)	
ARNICA MONTANA FLOWER (UNII: OZ0E5Y15PZ)	
FD&C BLUE NO. 1 (UNII: HBR47K3TBD)	
BUTYLENE GLYCOL (UNII: 3XUS85K0RA)	
CALENDULA OFFICINALIS FLOWER (UNII: P0M7O4Y7YD)	
CAPSICUM (UNII: 00UK7646FG)	
CARBOMER 934 (UNII: Z135WT9208)	
CENTAUREA CYANUS FLOWER (UNII: QZ239038YC)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128MIS)	
CORIANDER OIL (UNII: 7626GC95E5)	
EMU OIL (UNII: 344821WD61)	
HAMAMELIS VIRGINIANA TOP (UNII: UDA30A2JJY)	
HYPERICUM PERFORATUM (UNII: XK4IUX8MNB)	
CHAMOMILE (UNII: FGL3685T2X)	
DIMETHYL SULFONE (UNII: 9H4PO4Z4FT)	
WATER (UNII: 059QF0K00R)	
SALIX ALBA BARK (UNII: 205MXS71H7)	
ISOPROPYL ALCOHOL (UNII: ND2M416302)	
SORBITOL (UNII: 506T60A25R)	
EDETATE SODIUM (UNII: MP1J8420LU)	
TILIA X EUROPAEA FLOWER (UNII: NHV2K10UDH)	
TROLAMINE (UNII: 9O3K93S3TK)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:58133-001-13	113 g in 1 TUBE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	03/15/2013	

Labeler - Cosmetic Specialty labs, Inc. (032973000)

Establishment

Name	Address	ID/FEI	Business Operations
Cosmetic Specialty labs, Inc.		032973000	manufacture(58133-001)

Revised: 3/2013

Cosmetic Specialty labs, Inc.