

PAIN RELIEF CREAM TOPICAL ANALGESIC- menthol 6% 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.

Dr. Wolfe's OTC Energized Pain Relief Cream

Drug Facts

Active Ingredient

Menthol 6.0%

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
- do not bandage tightly
- 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 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 Barbadensis Leaf Juice, Anthemis nobilis (Roman Chamomile), Arnica montana, Butylene glycol, Calendula officinalis (Marigold), Capryl glycol, Calpsicum grutescens, Carbomer, Cantharius tinctorious (Safflower) Seed Oil, Centaureacyanus (Cornflower), Cetearyl alcohol, Cetyl alcohol, Chamomila recutita (Matricaria Chamomila), Coriandrum sativum (Coriander), Hamamelis virginiana (Witch Hazel), Bark/Leaf/Twig, Hypericum perforatum (St. John's Wort), Industrial Hemp geed oil, Methylsulfonylmethane, Phenoxyethanol, Purified water, Salix alba (Willow Bark), SD Alcohol40, Sorbitol, Tetrasodium EDTA, Tilla cordata (Lime Tree), Triethanolamine

Manufactured for: Good Energy Products

a DBA of Special Effort Ltd. Austin, TX 78701

www.goodenergyproducts.com (800) 698-ALOE

Made in the U.S.A.

PRINCIPAL DISPLAY PANEL



Tested & Proven
to be effective for
Arthritis, Simple Backache,
Muscle Strains & Sprains

Organic Aloe Vera
+ Hemp Oil

Net Wt. 2.75 Fl. Oz (81 mL)

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Menthol 6.0%	Topical analgesic

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■ 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

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 Juice, Anthemis nobilis (Roman Chamomile), Amica montana Flower, Butylene Glycol, Calendula officinalis (Marigold), Caprylyl Glycol, Capsicum Frutescens Fruit, Carbomer, Carthamus tinctorius (Safflower) Seed Oil, Centaurea cyanus (Comflower), Celsaryl Alcohol, Cetyl Alcohol, Chamomilla recutita (Matricaria Chamomilla), Coriandrum sativum (Coriander) Fruit Oil, Hamamelis virginiana (Witch Hazel) Bark/Leaf/Twig, Hypericum perforatum (St. John's Wort), Industrial Hemp Seed Oil, Methylsulfonylmethane, Phenoxyethanol, Purified Water, Salix alba (Willow) Bark, SD Alcohol 40, Sorbitol, Tetrasodium EDTA, Tilia cordata (Lime Tree), Triethanolamine.

NDC 58133-222-03



5054099

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PAIN RELIEF CREAM TOPICAL ANALGESIC

menthol 6% cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:58133-222
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	6 g in 100 mL

Inactive Ingredients

Ingredient Name	Strength
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
TRIETHANOLAMINE LAURYLAMINOPROPIONATE (UNII: 793J74ICPW)	
MATRICARIA CHAMOMILLA (UNII: G0R4UBI2ZZ)	
CHAMAEMELUM NOBILE FLOWER (UNII: O2T154T6OG)	
ARNICA MONTANA FLOWER (UNII: OZ0E5Y15PZ)	
CALENDULA OFFICINALIS FLOWER (UNII: P0M7O4Y7YD)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
CAPSICUM (UNII: 00UK7646FG)	
CARBOMER HOMOPOLYMER TYPE B (ALLYL SUCROSE CROSSLINKED) (UNII: Z135WT9208)	
CENTAUREA CYANUS FLOWER (UNII: QZ239038YC)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	
CETYL ALCOHOL (UNII: 936JST6JCN)	
CORIANDER OIL (UNII: 7626GC95E5)	
HAMAMELIS VIRGINIANA TOP (UNII: UDA30A2JJY)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
WATER (UNII: 059QF0K00R)	
SALIX ALBA BARK (UNII: 205MXS71H7)	
ISOPROPYL ALCOHOL (UNII: ND2M416302)	
SORBITOL (UNII: 506T60A25R)	
TILIA X EUROPAEA FLOWER (UNII: NHV2K10UDH)	
HEMP (UNII: TD1MUT01Q7)	
BUTYLENE GLYCOL (UNII: 3XUS85K0RA)	
HYPERICUM PERFORATUM (UNII: XK4IUX8MNB)	
3-((3-CHLOROPHENYL)(4-(METHYLSULFONYL)PHENYL)METHYLENE)DIHYDRO-2(3H)-FURANONE, (3Z)- (UNII: 920350682Z)	
DITETRACYCLINE TETRASODIUM EDETATE (UNII: WX0A0IT7K5)	
CARTHAMUS TINCTORIUS FLOWER OIL (UNII: SDQ136WIM5)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:58133-222-03	81 mL in 1 TUBE; Type 0: Not a Combination Product	10/31/2018	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	10/31/2018	

Labeler - Cosmetic Specialty labs, Inc. (032973000)

Establishment

Name	Address	ID/FEI	Business Operations
Cosmetic Specialty labs, Inc.		032973000	manufacture(58133-222)

Revised: 10/2018

Cosmetic Specialty labs, Inc.