

INFLAMMATION OTC DEEP PAIN CARE COLD- camphor, menthol lotion

Skin Deep

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.

Drug Facts

Active Ingredient

Camphor (3.0%)

Menthol (2.6%)

Purpose

Topical Analgesic

Counterirritant

Uses

For temporary relief of minor aches and pains of muscles and joints associated with

- simple backache
- arthritis
- strains
- sprains

Warnings

For external use only

Avoid contact with the eyes

If condition worsens, or if symptoms persist for more than 7 days or clear up and occur again within a few days, discontinue use of this product and consult a physician

Do not apply to wounds or damaged skin

Do not bandage tightly

Keep out of reach of children

In case of accidental ingestion seek professional assistance or contact a poison control immediately

Directions

Adults and children 2 years of age and older- Apply to affected area not more than 3 to 4 times daily.

Children under 2 years of age- Consult a physician.

Inactive Ingredients

water, dimethyl sulfone, glycerin, glycine soja (soybean) oil, eucalyptus globulus oil, piper nigrum (pepper) seed extract, centipedia cunninghamii extract, arctium majus root (burdock) extract, mentha piperita (peppermint) leaf extract, artemisia absinthium, uncaria tomentosa extract, zingiber officinale

(ginger) root oil, arnica montana flower extract, zingiber officinale (ginger) root extract, d-ribose, sodium polycrylate, c18-21 alkane, trideceth-6, tocopherol, phenoxyethanol, iodopropynyl butylcarbamate

Questions or Comments

Store between 35 F and 80 F

call 1-912-236-9430 weekdays

Principal Display Panel

Inflammation OTC

Deep Pain Care Cold

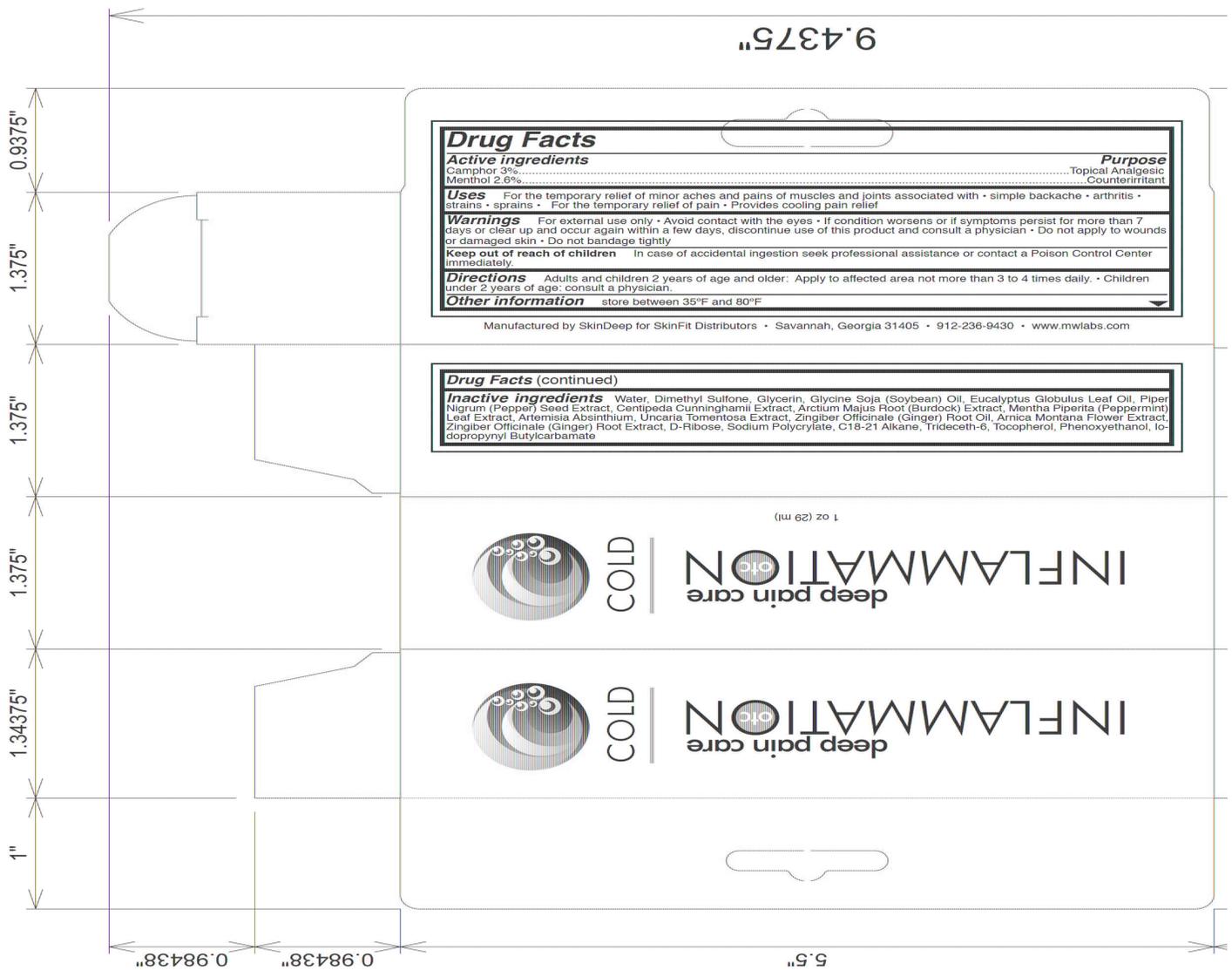
New wt 1.1 oz. (31 mL)

Manufactured by SkinDeep for SkinFit Distributors

Savannah, GA 31405

Tel: 912-236-9430

www.mwlab.com



INFLAMMATION OTC DEEP PAIN CARE COLD			
camphor, menthol lotion			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:45156-56 10
Route of Administration	TOPICAL		
Active Ingredient/Active Moiety			
Ingredient Name		Basis of Strength	Strength
Camphor (Natural) (UNII: N20HL7Q941) (Camphor (Natural) - UNII:N20HL7Q941)		Camphor (Natural)	18 g in 600 g
Menthol (UNII: L7T10EIP3A) (Menthol - UNII:L7T10EIP3A)		Menthol	16 g in 600 g
Inactive Ingredients			
Ingredient Name			Strength

Water (UNII: 059QF0KO0R)	
Glycerin (UNII: PDC6A3C0OX)	
Dimethyl Sulfone (UNII: 9H4PO4Z4FT)	
Black Pepper Oil (UNII: U17J84S19Z)	
Soybean Oil (UNII: 241ATL177A)	
Arctium Lappa Root (UNII: 597E9BI3Z3)	
Peppermint (UNII: V95R5KMY2B)	
Wormwood (UNII: F84709P2XV)	
Cat's Claw (UNII: 9060PRM18Q)	
Ginger Oil (UNII: SAS9Z1SVUK)	
Arnica Montana (UNII: O80TY208ZW)	
Ginger (UNII: C5529G5JPQ)	
Trideceth-6 (UNII: 3T5PCR2H0C)	
Alpha-Tocopherol (UNII: H4N855PNZ1)	
Phenoxyethanol (UNII: HIE492ZZ3T)	
Iodopropynyl Butylcarbamate (UNII: 603P14DHEB)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:45156-5610-2	1 in 1 BOX		
1	NDC:45156-5610-1	31 g in 1 TUBE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part348	08/16/2011	

Labeler - Skin Deep (833276566)

Establishment

Name	Address	ID/FEI	Business Operations
Skin Deep		833276566	manufacture

Revised: 8/2011

Skin Deep