

INFLAMMATION OTC DEEP PAIN CARE HOT- camphor, capsicum, 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 Fact

Active Ingredient

Camphor (0.46%)

Capsicum Annuum Extract (0.025%)

Menthol (1.7%)

Purpose

Topical Analgesic

Counterirritant

Counterirritant

Uses

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

- simple backache
- arthritis
- strains
- sprains

For the temporary relief of pain

Provides warming pain relief

Warnings

For external use only

Avoid contact with the eyes

Do not apply to wounds or damaged skin

Do not bandage tightly

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

Keep out of reach of children

In case of accidental ingestion seek professional assistance or contact a poison control center 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 sulfonate, glycerin, glycine soja (soybean) oil, eucalyptus globulus oil, piper nigrum (pepper) seed extract, sodium polycrylate, c18-21 alkane, niacinamide, artemisia absinthium, uncaria tomentosa extract, juniperus communis fruit oil, xanthan gum, zingiber officinate (ginger) root extract, arctium majus root (burdock) extract, arnica montana flower extract, trideceth-6, tocopherol, phenoxyethanol, iodopropynyl butylcarbamate

Questions and Comments

store between 35 F and 80 F

call 1-912-236-9430 weekdays

Principal Display Panel

Inflammation OTC

Deep Pain Care Hot

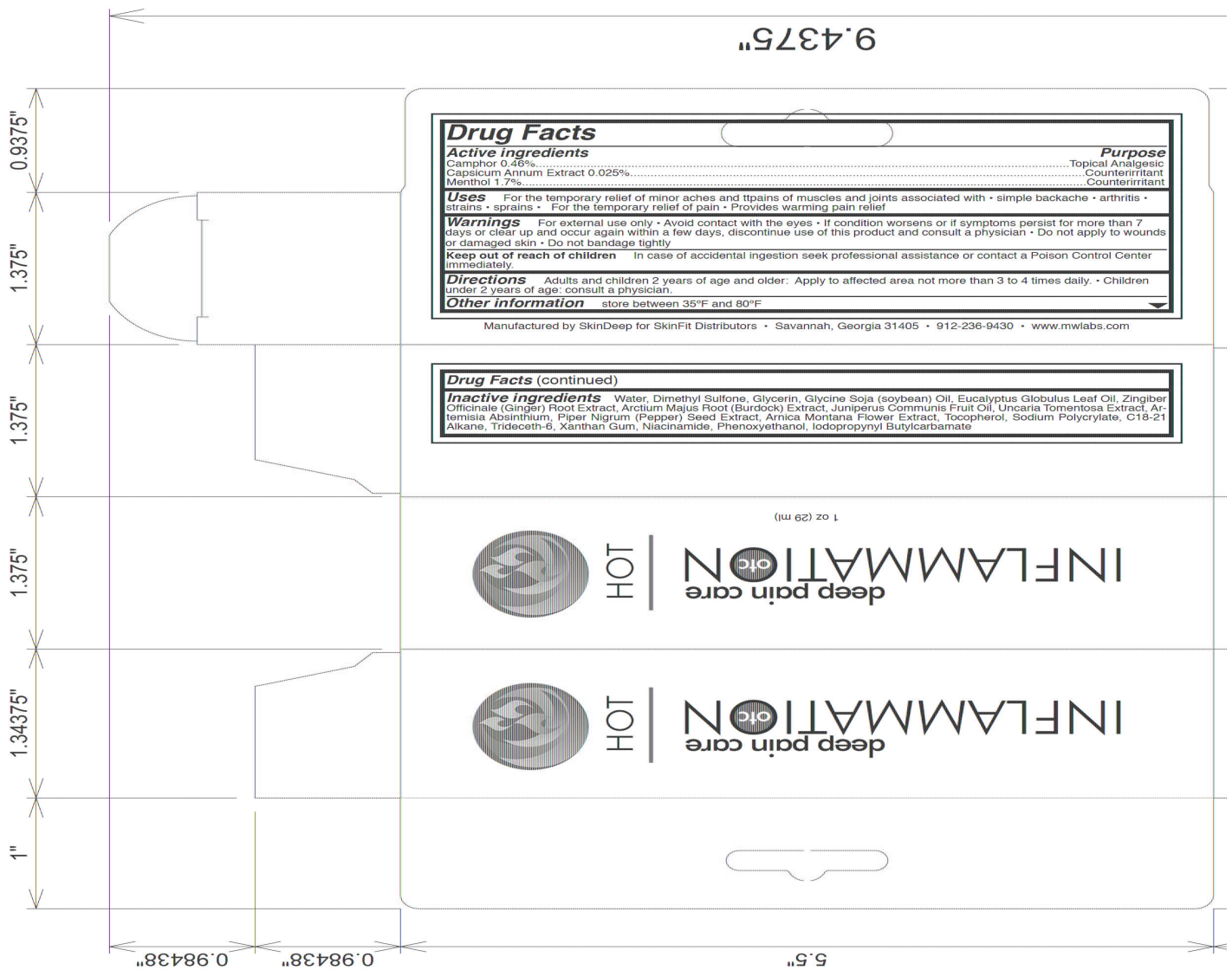
New wt 1.1 oz. (31 mL)

Manufactured by SkinDeep for SkinFit Distributors

Savannah, GA 31405

Tel: 1-912-236-9430

www.mwllabs.com



INFLAMMATION OTC DEEP PAIN CARE HOT

camphor, capsicum, menthol lotion

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:45156-5605
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Camphor (Natural) (UNII: N20HL7Q941) (Camphor (Natural) - UNII:N20HL7Q941)	Camphor (Natural)	4 g in 1000 g
Capsicum (UNII: 00UK7646FG) (Capsicum - UNII:00UK7646FG)	Capsicum	38 g in 1000 g
Menthol (UNII: L7T10EIP3A) (Menthol - UNII:L7T10EIP3A)	Menthol	17 g in 1000 g

Inactive Ingredients

Ingredient Name	Strength
Water (UNII: 059QF0KO0R)	

Glycerin (UNII: PDC6A3C0OX)
Dimethyl Sulfone (UNII: 9H4PO4Z4FT)
Ginger (UNII: C5529G5JPQ)
Soybean Oil (UNII: 241ATL177A)
Arctium Lappa Root (UNII: 597E9B13Z3)
Juniper Berry Oil (UNII: SZH16H44UY)
Cat's Claw (UNII: 9060PRM18Q)
Wormwood (UNII: F84709P2XV)
Black Pepper (UNII: KM66971LVF)
Arnica Montana Flower (UNII: OZ0E5Y15PZ)
Alpha-Tocopherol (UNII: H4N855PNZ1)
Xanthan Gum (UNII: TTV12P4NEE)
Niacinamide (UNII: 25X51I8RD4)
Phenoxyethanol (UNII: HIE492ZZ3T)
Iodopropynyl Butylcarbamate (UNII: 603P14DHEB)
Corymbia Citriodora Leaf Oil (UNII: M63U6N96EB)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:45156-5605-2	1 in 1 BOX		
1	NDC:45156-5605-1	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