

HOT STUFF- capsicum oleoresin cream
Mueller Sports Medicine LLC

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.

Hot Stuff®

Drug Facts

Active ingredient

Capsicum Oleoresin 0.0625%
(Containing Capsaicin 0.025%)

Purpose

Pain Relief

Uses

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

- simple backache
- arthritis
- strains
- sprains

Warnings

For external use only.

- do not apply to wounds or damaged skin
- do not bandage tightly
- do not use with heating pad, pack, wrap, hot water bottle or any heating element

When using this product do not get into eyes

- avoid contact with other mucous membranes

Discontinue use and ask a doctor if condition worsens or if symptoms persist for more than 7 days or clear up and occur again within a few days

Keep out of reach of children.

- if swallowed, get medical help or contact a Poison Control center right away
- **if pregnant or nursing**, seek the advice of a health professional before using

Directions

- **Rotate pump's spout counter-clockwise slightly to unlock; clockwise to lock**
- Children under 12 years of age consult a physician
- Apply a thin layer to affected area not more than 3 to 4 times daily
- Gently massage into the skin until fully absorbed
- Wash hands with soap and water after each application to avoid spreading to the eyes or other sensitive mucous membranes

- A burning sensation may occur upon initial application but generally disappears with continued use
- For a severe burning discomfort, remove excess product with a soft cloth and mineral oil

Inactive ingredients

Water (Aqua), Butylene Glycol, Glycerin, Aloe Barbadensis Leaf Juice, Helianthus Annuus (Sunflower) Seed Oil, Medicago Sativa (Alfalfa) Extract, Arnica Montana Flower Extract, Cymbopogon Schoenanthus Stem/Leaf/Flower Extract, Rosmarinus Officinalis (Rosemary) Leaf Extract, Mentha Piperita (Peppermint) Leaf Extract, Panax Ginseng Root Extract, Ginkgo Biloba Leaf Extract, Linum Usitatissimum (Linseed) Seed Extract, Celosia Argentea Seed Extract, Euterpe Oleracea Fruit Extract, Mentha Piperita (Peppermint) Oil, Glucosamine HCl, Dimethyl Sulfone, Hydrolyzed Corn Starch, Lauryl Laurate, Methyl Diisopropyl Propionamide, Ethyl Mentane Carboxamide, Menthyl Lactate, Hydrated Silica, Zea Mays (Corn) Starch, Hydrolyzed Corn Starch Octenylsuccinate, Cetearyl Isononanoate, Ceteareth-20, Cetearyl Alcohol, Glyceryl Stearate, Ceteareth-12, Cetyl Palmitate, Emu Oil, Polysorbate 20, Acrylates/C 10-30 Alkyl Acrylate Crosspolymer, Tocopheryl Acetate, Disodium EDTA, Phenoxyethanol, Caprylyl Glycol, Ethylhexylglycerin, Hexylene Glycol, Sodium Hydroxide

Questions or comments?

Call 1-800-356-9522 or Email us at sportcare@muellersportsmed.com

PRINCIPAL DISPLAY PANEL - 106 g Bottle Label

MUELLER®

Hot Stuff®

Cream

topical analgesic

*Warming Capsaicin formula
delivers comforting,
targeting relief*

**HELPS TO RELIEVE PAIN
ASSOCIATED WITH**

- *Strains*
- *Sprains*
- *Muscle Aches & Pain*
- *Arthritis*
- *Joint Pain*

6h

Timed-Release

IcePearls™

30805 LBL30805A - 9.16

NET WT 3.75 OZ (106 g)



Hot Stuff[®] Cream

topical analgesic

Warming **Capsaicin** formula delivers comforting, targeting relief

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EXTRACT, 1 AND 2 GINSENG ROOT EXTRACT, GINKGO BILOBA LEAF EXTRACT, Linum Usitatissimum (Linseed) Seed Extract, Celosia Argentea Seed Extract, Euterpe Oleracea Fruit Extract, Mentha Piperita (Peppermint) Oil, Glucosamine HCl, Dimethyl Sulfone, Hydrolyzed Corn Starch, Lauryl Laurate, Methyl Diisopropyl Propionamide, Ethyl Mentane Carboxamide, Menthyl Lactate, Hydrated Silica, Zea Mays (Corn) Starch, Hydrolyzed Corn Starch Octenylsuccinate, Cetearyl Isononanoate, Cetearth-20, Cetearyl Alcohol, Glyceryl Stearate, Cetearth-12, Cetyl Palmitate, Emu Oil, Polysorbate 20, Acrylates/C 10-30 Alkyl Acrylate Crosspolymer, Tocopheryl Acetate, Disodium EDTA, Phenoxyethanol, Caprylyl Glycol, Ethylhexylglycerin, Hexylene Glycol, Sodium Hydroxide

Questions or comments? Call 1-800-356-9522 or Email us at sportcare@muellersportsmed.com

Mktd by: Mueller Sports Medicine, Inc.
Prairie du Sac, WI 53578 USA

HOT STUFF

capsicum oleoresin cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:52564-308
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
CAPSICUM OLEORESIN (UNII: UW86K581WY) (CAPSICUM OLEORESIN - UNII:UW86K581WY)	CAPSAICIN	0.0265 g in 106 g

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
BUTYLENE GLYCOL (UNII: 3XUS85K0RA)	
GLYCERIN (UNII: PDC6A3C0OX)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
SUNFLOWER OIL (UNII: 3W1JG795YI)	
ALFALFA (UNII: DJO934BRBD)	
ARNICA MONTANA FLOWER (UNII: OZ0E5Y15PZ)	
ROSEMARY (UNII: IJ67X351P9)	
MENTHA PIPERITA LEAF (UNII: A389O33LX6)	
ASIAN GINSENG (UNII: CUQ3A77YXI)	
GINKGO (UNII: 19FUJ2C58T)	
FLAX SEED (UNII: 4110YT348C)	

ACAI (UNII: 46AM2VJ0AW)
PEPPERMINT OIL (UNII: AV092KU4JH)
GLUCOSAMINE HYDROCHLORIDE (UNII: 750W5330FY)
DIMETHYL SULFONE (UNII: 9H4PO4Z4FT)
LAURYL LAURATE (UNII: GPW77G0937)
METHYL DIISOPROPYL PROPIONAMIDE (UNII: 6QOP5A9489)
ETHYL MENTHANE CARBOXAMIDE (UNII: 6S7S02945H)
MENTHYL LACTATE, (-)- (UNII: 2BF9E65L7I)
HYDRATED SILICA (UNII: Y6O7T4G8P9)
STARCH, CORN (UNII: O8232NY3SJ)
CETEARYL ISONONANOATE (UNII: P5O01U99NI)
POLYOXYL 20 CETOSTEARYL ETHER (UNII: YRC528SWUY)
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)
CETEARETH-12 (UNII: 7V4MR24V5P)
CETYL PALMITATE (UNII: 5ZA2S6B08X)
EMU OIL (UNII: 344821WD61)
POLYSORBATE 20 (UNII: 7T1F30V5YH)
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)
EDETATE DISODIUM ANHYDROUS (UNII: 8NLQ36F6MM)
PHENOXYETHANOL (UNII: HIE492ZZ3T)
CAPRYLYL GLYCOL (UNII: 00YIU5438U)
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)
HEXYLENE GLYCOL (UNII: KEH0A3F75J)
SODIUM HYDROXIDE (UNII: 55X04QC32I)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:52564-308-02	106 g in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	11/01/2016	
2	NDC:52564-308-01	106 g in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	06/25/2014	03/01/2018

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH NOT FINAL	part348	06/25/2014	

Labeler - Mueller Sports Medicine LLC (006426316)