TRIPLE POWER PAIN RELIEF- menthol, unspecified form and camphor (synthetic) cream Concept Laboratories, 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.

Triple Power Pain Relief

Drug Facts

Active ingredient	Purpose
Menthol 12%	Pain Relieving
Camphor 6%	Pain Relieving

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

Extremely Flammable: Keep from heat and flame.

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

Inactive ingredients

Water (Aqua), Aloe Barbadensis Leaf Juice, SD Alcohol 40-B, Propylene Glycol, Mentha Piperita (Peppermint) Oil, Arnica Montana Flower Extract, Carbomer, Acrylates Copolymer, Corn Starch Modified, Linum Usitatissimum (Linseed) Seed Oil, Euterpe Oleracea Fruit Oil, PPG-2 Hydroxyethyl Cocamide, Rosmarinus Officinalis (Rosemary) Leaf Oil, Methyl Diisopropyl Propionamide, Ethyl Menthane Carboxamide, Menthyl Lactate, Lauryl Laurate, Zea Mays (Corn) Starch, Hydrolyzed Corn Starch, Hydrolyzed Starch Octenylsuccinate, Phenoxyethanol (Phenagon PDI), DMDM Hydantoin, Iodopropynyl Butylcarbamate.

Questions or comments?

Call 1-888-373-8831 or visit us at www.conceptlabs.org

PRINCIPAL DISPLAY PANEL - 106 g Bottle Label

TRIPLE POWER PAIN RELIEF

SUPER COOLING FAST ACTING

MENTHOL & CAMPHOR

+ ARNICA, ROSEMARY & ACAI

NET WT 3.75 OZ (106 g)

Drug Facts

Active ingredient

Menthol 12% Camphor 6%

Purpose

Pain Relieving Pain Relieving

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

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Concept Laboratories, Inc. Chicago, IL 60642 (USA) #CL10120



TRIPLE POWER PAIN RELIEF SUPER COOLING FAST ACTING

MENTHOL & CAMPHOR



NET WT 3.75 OZ. (106 g)

TRIPLE POWER PAIN RELIEF

menthol, unspecified form and camphor (synthetic) cream

Product Information

Product Type HUMAN OTC DRUG Item Code (Source) NDC:64058-341

Route of Administration TOPICAL

Active Ingredient/Active Moiety

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	Ingredient Name	Basis of Strength	Strength
MENTHOL, UNSPECIFIED FORM	(UNII: L7T10EIP3A) (MENTHOL, UNSPECIFIED FORM -	MENTHOL, UNSPECIFIED	0.12 g

UNII:L7T10EIP3A)	FORM	in 1 g
CAMPHOR (SYNTHETIC) (UNII: 5TJD82A1ET) (CAMPHOR (SYNTHETIC) - UNII:5TJD82A1ET)	CAMPHOR (SYNTHETIC)	0.06 g in 1 g

Inactive Ingredients	
Ingredient Name	Strength
Water (UNII: 059QF0KO0R)	
ALOE VERA LEAF (UNII: ZY8 1Z8 3H0 X)	
PROPYLENE GLYCOL (UNII: 6 DC9 Q167V3)	
PEPPERMINT OIL (UNII: AV092KU4JH)	
ALCOHOL (UNII: 3K9958V90M)	
STARCH, CORN (UNII: O8232NY3SJ)	
ARNICA MONTANA FLOWER (UNII: OZ0E5Y15PZ)	
LINSEED OIL (UNII: 84XB4DV00W)	
ROSEMARY OIL (UNII: 8LGU7VM393)	
ACAI OIL (UNII: Z0W6766A2W)	
PPG-2 HYDRO XYETHYL CO CAMIDE (UNII: 34N07GUJ3X)	
METHYL DIISOPROPYL PROPIONAMIDE (UNII: 6QOP5A9489)	
ETHYL MENTHANE CARBO XAMIDE (UNII: 6S7S02945H)	
MENTHYL LACTATE, (-)- (UNII: 2BF9E65L7I)	
LAURYL LAURATE (UNII: GPW77G0937)	
DMDM HYDANTO IN (UNII: BYR0546 TOW)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
IODOPROPYNYL BUTYLCARBAMATE (UNII: 603P14DHEB)	

ı	Pá	ackaging			
ı	#	Item Code	Package Description	Marketing Start Date	Marketing End Date
ı	1	NDC:64058-341-64	106 g in 1 BOTTLE; Type 0: Not a Combination Product		

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH NOT FINAL	part348	06/25/2015	

Labeler - Concept Laboratories, Inc. (962282612)

Establishment			
Name	Address	ID/FEI	Business Operations
Concept Laboratories, Inc.		962282612	MANUFACTURE(64058-341)

Revised: 6/2015 Concept Laboratories, Inc.