

CAPASIL PAIN RELIEVING- menthol, methyl salicylate cream

PureTek Corporation

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.

Capasil

Active ingredients

Menthol 2.0%..... Topical Analgesic
Methyl Salicylate 10%...Topical Analgesic

Purpose

Topical Analgesic

Keep out of reach of children.

If swallowed, get medical help or contact a Poison Control Center right away.

Uses

For the temporary relief of minor aches and pains of muscles and joints associated with simple backache, arthritis, strains, bruises, sprains.

Warnings

For external use only.

Do not

- apply on wounds or damaged skin
- bandage tightly

When using this product

avoid contact with the eyes

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

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 doctor.

Inactive ingredients

Aloe Barbadensis(Aloe Vera) Leaf Juice Powder, Aqua (Purified Water), Borago Officinalis Seed Oil, Carbomer, Cetareth-20, Cetaryl Alcohol, Cetyl Alcohol, DL-alpha-tocopheryl

acetate, Eucalyptus Globulus Leaf Oil, Fragrance, Fructose, Phenoxyethanol, Propylene Glycol, Squalane, Stearic Acid, Stearyl Alcohol, Sodium Hydroxide, Tetrasodium EDTA, Vitis Vinifera (Grape) Seed Oil.

Store at controlled room temperature 20°-25°C (68°-77°F).

Label

Manufactured in the USA by:
 PureTek Corporation
 Panorama City, CA 91402
 Questions? Call toll-free: 1-877-921-7873
 List No: 43405 JPA Rev. 36981

NDC 59088-434-05

Pain Relieving Cream
 with Menthol 2.0% and Methyl Salicylate 10%
PROVIDES RELIEF for ARTHRITIS and MUSCLE PAIN
 2 fl. oz. (59 ml)

Drug Facts	Purpose Active ingredients Menthol 2.0% Methyl Salicylate 10.0% Typical Analgesic Typical Analgesic
Uses	For the temporary relief of minor aches and pains or muscle aches and pains associated with the common cold, flu, sore throat, headache, toothache, and minor burns, sunburn, and sprains.
Warnings	For external use only Do not apply on wounds or damaged skin Do not bandage tightly When using this product, avoid contact with the eyes or mucous membranes Do not use other than as directed 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 Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.
Directions	Adults and children 12 years of age and older: apply to affected area not more than 3 to 4 times daily. Children under 12 years of age: consult a doctor.
Other information	Store at controlled room temperature 20°-25°C (68°-77°F).
Inactive ingredients	Alve Barbadensis (Aloe Vera) Leaf Juice Powder, Aqua (Purified Water), Benzoin Officinalis Seed Oil, Carbomer, Cetyl Alcohol, DL-alpha-tocopheryl acetate, Eucalyptus Globulus Leaf Oil, Fragrance, Fructose, Phenoxyethanol, Propylene Glycol, Squalane, Stearic Acid, Stearyl Alcohol, Sodium Hydroxide, Tetrasodium EDTA, Vitis Vinifera (Grape) Seed Oil.

CAPASIL PAIN RELIEVING

menthol, methyl salicylate cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:59088-434
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
METHYL SALICYLATE (UNII: LAV5U5022Y) (SALICYLIC ACID - UNII:O414PZ4LPZ)	METHYL SALICYLATE	100 mg in 1 mL
MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	20 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
MENHADEN OIL (UNII: 1D8HWC57D0)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
AMINOMETHYL PROPANEDIOL (UNII: CZ7BU4QZJZ)	
LIMONENE, (+)- (UNII: GFD7C86Q1W)	
PALMITIC ACID (UNII: 2V16EO95H1)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
BORAGE SEED OIL (UNII: F8XAG1755S)	
CARBOMER HOMO POLYMER TYPE B (ALLYL SUCROSE CROSSLINKED) (UNII: Z135WT9208)	
POLYOXYL 20 CETOSTEARYL ETHER (UNII: YRC528SWUY)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	
CETYL ALCOHOL (UNII: 936JST6JCN)	
EUCALYPTUS OIL (UNII: 2R04ONI662)	
FRUCTOSE (UNII: 6YSS42VSEV)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
WATER (UNII: 059QF0K00R)	
SQUALANE (UNII: GW89575KF9)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
STEARYL ALCOHOL (UNII: 2KR89I4H1Y)	
EDETATE SODIUM (UNII: MP1J8420LU)	

.ALPHA.-TOCOPHEROL ACETATE, DL- (UNII: WR1WPI7EW8)

GRAPE SEED OIL (UNII: 930MLC8XGG)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:59088-434-05	59 mL in 1 JAR; Type 0: Not a Combination Product	10/14/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	10/14/2020	

Labeler - PureTek Corporation (785961046)

Revised: 10/2020

PureTek Corporation