

MENCYLATE 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.

Mencylate

Active ingredients

Menthol 2.0%
Methyl Salicylate 10.0%

Purpose

Topical Analgesic

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 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:

Aloe Barbadensis (Aloe Vera) Leaf Juice Powder, Aqua (Purified Water), Borago Officinalis Seed Oil, Carbomer, Cetareth-20, Cetearyl 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.

Mencylate™

Manufactured in the USA by:
 PureTek Corporation
 Panorama City, CA 91402
 Questions? Call toll-free: 1-877-921-7873

Manufactured in the USA by: PureTek Corporation Panorama City, CA 91402 Questions? Call toll-free: 1-877-921-7873 List No: 21505IAA Rev. 38631 	NDC 59088-215-05  Pain Relieving Cream with Menthol 2.0% and Methyl Salicylate 10% PROVIDES RELIEF for ARTHRITIS and MUSCLE PAIN 2 fl. oz. (59 ml)	<table border="1"> <tr> <td style="width: 15%;">Drug Facts</td> <td> Purpose Analgesic Methyl Salicylate 10.0%, Topical Analgesic Menthol 2.0% </td> </tr> <tr> <td>Uses</td> <td> For the temporary relief of minor aches and pains of muscles and joints associated with simple headache, arthritis, sprains, strains, and contusions. </td> </tr> <tr> <td>Warnings</td> <td> For external use only. Do not apply on wounds or damaged skin. 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. </td> </tr> <tr> <td>Directions</td> <td> 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. </td> </tr> <tr> <td>Other information</td> <td> Store at controlled room temperature 20°-25°C (68°-77°F). Inactive Ingredients: Aloe Barbadensis (Aloe Vera) Leaf Juice Powder, Aqua (Purified Water), Borago Officinalis Seed Oil, Carbomer, Cetareth-20, 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. </td> </tr> </table>	Drug Facts	Purpose Analgesic Methyl Salicylate 10.0%, Topical Analgesic Menthol 2.0%	Uses	For the temporary relief of minor aches and pains of muscles and joints associated with simple headache, arthritis, sprains, strains, and contusions.	Warnings	For external use only. Do not apply on wounds or damaged skin. 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: Aloe Barbadensis (Aloe Vera) Leaf Juice Powder, Aqua (Purified Water), Borago Officinalis Seed Oil, Carbomer, Cetareth-20, 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.
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MENCYLATE PAIN RELIEVING

menthol, methyl salicylate cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:59088-215
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
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
BORAGE SEED OIL (UNII: F8XAG1755S)	

CARBOMER 934 (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)
SODIUM HYDROXIDE (UNII: 55X04QC32I)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:59088-215-05	59 mL in 1 JAR; Type 0: Not a Combination Product	03/24/2023	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	03/24/2023	

Labeler - PureTek Corporation (785961046)

Revised: 3/2023

PureTek Corporation