MYORX LOW DOSE PAIN RELIEVING - menthol 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.

Drug Facts

Active ingredient

Menthol 0.5%

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, Borago Officinalis Seed Oil, Capsaicin, Carbomer, Ceteareth-20, Cetearyl Alcohol, Cetyl Alcohol, Citric Acid, Eucalyptus Globulus Leaf Oil, Fructose, Menhaden Oil, Methyl Salicylate, Methylparaben, Phenoxyethanol, Propylene Glycol, Propylparaben, Purified Water, Squalane, Stearic Acid, Stearyl Alcohol, Tetrasodium EDTA, Tocopheryl Acetate

(Vitamin E), Triethanolamine, Vitis Vinifera (Grape) Seed Oil.

Store at controlled room temperature 59°-86°F (15°-30°C).

Label

MYORX LOW DOSE PAIN RELIEVING

menthol cream

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:59088-954
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	5 uL in 1 mL

Inactive Ingredients	
Ingredient Name	**Strength**
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
BORAGE OIL (UNII: F8XAG1755S)	
CAPSAICIN (UNII: S07O44R1ZM)	
CARBOMER 934 (UNII: Z135WT9208)	
POLYOXYL 20 CETOSTEARYL ETHER (UNII: YRC528SWUY)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	
CETYL ALCOHOL (UNII: 936JST6JCN)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
EUCALYPTUS OIL (UNII: 2R04ONI662)	
FRUCTOSE (UNII: 6YSS42VSEV)	
HYDROGENATED MENHADEN OIL (UNII: 736VD7888J)	
METHYL SALICYLATE (UNII: LAV5U5022Y)	

METHYLPARABEN (UNII: A2I8C7HI9T)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
PROPANEDIOL (UNII: 5965N8W85T)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
WATER (UNII: 059QF0KO0R)	
SQUALANE (UNII: GW89575KF9)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
STEARYL ALCOHOL (UNII: 2KR89I4H1Y)	
EDETATE SODIUM (UNII: MP1J8420LU)	
.ALPHA.-TOCOPHEROL ACETATE, DL- (UNII: WR1WPI7EW8)	
TROLAMINE (UNII: 9O3K93S3TK)	
GRAPE SEED OIL (UNII: 930MLC8XGG)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:59088-954-05	59 mL in 1 JAR		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	07/01/2011	

Labeler - PureTek Corporation (785961046)

Establishment

Name	Address	ID/FEI	Business Operations
PureTek Corporation		785961046	manufacture, label, pack, outsourcing human drug compounding, relabel, repack

Revised: 7/2011 PureTek Corporation