

PAINZONE LIGHT- painzone light cream
MEDZONE PRODUCTS 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.

PainZone Light Cream

Active Ingredient

Active Ingredient	Use
Menthol 3.5%	Topical Analgesic

Uses

Uses:

- For temporary relief of minor aches and pains. Used for muscle and joint pain associated with arthritis, backache, strains, sprains

Do Not Use

Do not use:

- On wounds or damaged skin
- With a heating pad
- On children under 12 years of age
- If pregnant or breast feeding

Stop use and ask a physician if:

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- Condition worsens or symptoms persist for more than 7 days
- Symptoms clear up and occur again within a few days
- Excessive skin irritation occurs

Directions

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Use only as directed

Adults and children 12 years of age and older, rub a thin layer to affected area 3-4 times daily

Children under 12 years of age consult a physician

Wash hands after applying

Storage

Store at 68-86 degrees with lid tightly closed

Inactive Ingredient

Alcohol Denaturated, Camphor, Carbomer, Ethylhexylglycerin, Glycerin, Jaanese Green tea (Camellia Sinesis) Extract, Laureth-4, Petrolatum, Pineapple (Ananas Sativus) Extract, Polysorbate 80, Propylene Glycol, Phenoxyethanol, Triethanolamine, Water

Warnings For External Use Only:

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- Avoid contact with eyes and mucous membranes. Do not bandage tightly

Distributed By

Distributed by: MedZone

Lenexa, Kansas

Ph 913-948-9663

www.medzonecorp.com



MedZone^{ns}
SINCE 2001

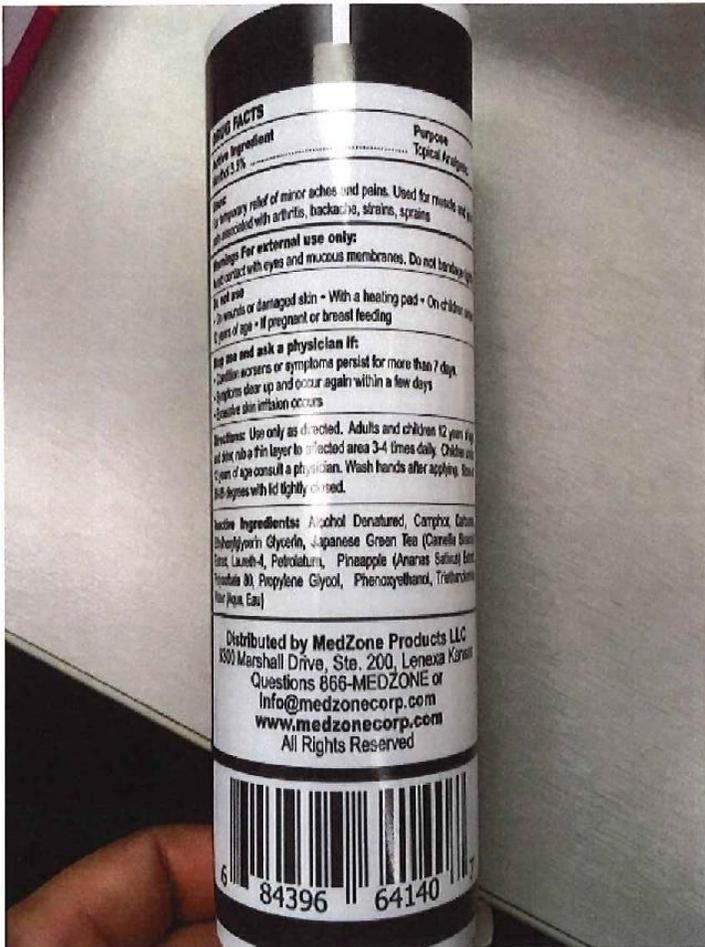
PainZone
PENETRATING PAIN RELIEF CREAM



- Helps With:**
- Sore Muscles & Joints
 - Arthritis Symptoms
 - Muscle Strain
 - Eases Back Pain
 - Deep Penetrating Relief
 - Sprains

MADE IN
USA

4 FL OZ



painzone light cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:70338-651
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	35 mg in 1 g

Inactive Ingredients

Ingredient Name	Strength
CAMPHOR (NATURAL) (UNII: N20HL7Q941)	
GREEN TEA LEAF (UNII: W2ZU1RY8B0)	
CARBOMER 940 (UNII: 4Q93RCW27E)	
GLYCERIN (UNII: PDC6A3C0OX)	
PETROLATUM (UNII: 4T6H12BN9U)	
LAURETH-4 (UNII: 6HQ855798J)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	
TRIETHANOLAMINE DODECYLBENZENESULFONATE (UNII: 8HM7ZD48HN)	
PROPYLENE GLYCOL 1-(2-METHYLBUTYRATE) (UNII: 9Q5W5G6461)	
ALCOHOL (UNII: 3K9958V90M)	
PINEAPPLE (UNII: 2A88ZO081O)	
WATER (UNII: 059QF0KO0R)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70338-651-01	113 g in 1 TUBE; Type 0: Not a Combination Product	01/01/2019	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	01/01/2019	

Labeler - MEDZONE PRODUCTS LLC (080083739)

Establishment

Name	Address	ID/FEI	Business Operations
Dhaliwal Laboratories LLC		016754201	manufacture(70338-651)

