

PAIN-X- menthol gel
OL PHARMA TECH,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.

Active ingredient

Menthol 2.5%

Purpose

Topical analgesic

Uses

temporarily relieves the minor aches and pains of muscles and joints associated with:

- simple backaches
- arthritis
- strains
- bruises
- sprains

Warnings

for external use only

Do not use

Do not use

- on wounds or damaged skin
- with a heating pad
- on a child under 12 years of age with arthritis-like conditions

Ask a doctor before use

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Ask a doctor before use if you have redness over the affected area.

When using this product

- avoid contact with eyes or mucous membranes
- do not bandage tightly

Stop use and ask a doctor 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

Keep out of reach of children

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center immediately.

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: ask a doctor

Other information

- store at 20° to 25°C (68° to 77°F)

Inactive ingredients

Vitamin E, Propylene glycol, Polysorbate 80, Water, Isopropyl alcohol, Carbomer interpolymer typ A, edta, Methylparaben, Propylparaben.

Questions

www.drspharmacyusa.com



PAIN-X

menthol gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:80489-003
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
MENTHOL, UNSPECIFIED FORM (UNII: L7T10EIP3A) (MENTHOL, UNSPECIFIED FORM - UNII:L7T10EIP3A)	MENTHOL, UNSPECIFIED FORM	25 mg in 1 g

Inactive Ingredients

Ingredient Name	Strength
CARBOMER INTERPOLYMER TYPE A (55000 CPS) (UNII: 59TL3WG5CO)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
ISOPROPYL ALCOHOL (UNII: ND2M416302)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
.ALPHA.-TOCOPHEROL (UNII: H4N855PNZ1)	
WATER (UNII: 059QF0K00R)	

Product Characteristics

Color	white (TRANSLUCENT)	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:80489-003-01	1 in 1 CARTON	01/01/2021	
1		28.3 g in 1 TUBE; Type 0: Not a Combination Product		
2	NDC:80489-003-02	1 in 1 CARTON	01/01/2021	
2		49.6 g in 1 TUBE; 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	01/01/2021	

Labeler - OL PHARMA TECH,LLC (021170377)

Registrant - OL PHARMA TECH,LLC (021170377)

Establishment

Name	Address	ID/FEI	Business Operations
OL PHARMA TECH,LLC (Drs. Pharmacy)		021170377	manufacture(80489-003)