

ATOPALM PAIN RELIEVING - menthol cream
NeoPharm Co., Ltd.

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.

ATOPALM PAIN RELIEVING CREAM

Drug Facts

Active ingredient

Menthol 10%

Purpose

Topical Analgesic

Uses For 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 use

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

Stop use and ask a doctor if

- conditions worsen
- symptoms persist for more than 7 days
- symptoms clear up and occur again within a few days
- excessive skin irritation occurs
- have redness over the affected area.

When using this product avoid contact with eyes or mucous membranes, do not bandage tightly.

Keep out of reach of children. If swallowed, get medical help immediately 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
ask a doctor

Inactive Ingredients

WATER, GLYCERIN, CETYL ALCOHOL, POLYSORBATE 60, GLYCERYL STEARATE, STEARIC ACID, DIMETHICONE, ISOPROPYL MYRISTATE, MYRISTOYL/PALMITOYL OXOSTEARAMIDE/ARACHAMIDE MEA, CARBOMER, TRIETHANOLAMINE, CHOLESTEROL, ALOE VERA GEL, METHYLPARABEN, PROPYLPARABEN.

Other Information

store at 20 - 25 degrees Celsius (68 - 75 degrees Fahrenheit)

see carton or flap or tube crimp for lot number and expiration date

Questions or information call toll free: 1-855-ATOPALM

US Patent # US 6221371B1

Distributed by: NeoPharm USA, 1 Oyster Bay Drive, Rumson, NJ 07760

Made in Korea

Pain Relieving Cream

Non-Greasy, Non-Staining

10% Menthol

Ultra-light Nighttime Scent

DEEP PENETRATING PAIN RELIEF

ATOPALM (TM)

Developed for Nighttime Use

Goes on smoothly and leaves skin feeling soft and smooth

Net. Wt. 2 oz/57 g

Specially Formulated with US Patented MLE Technology

DEEP PENETRATING PAIN RELIEF

ATOPALM™ PAIN RELIEVING CREAM

Specially Formulated with US Patented **M L E** Technology



Net Wt. 2 oz/57 g

Menthol 10%

Ultra-Light Nighttime Scent ■ Non-Staining ■ Non-Greasy

Active Ingredient Menthol 10%

Uses For 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 use on wounds or damaged skin ■ with a heating pad ■ on a child under 12 years of age with arthritis like conditions.

Stop use and ask a doctor if ■ conditions worsen ■ symptoms persist for more than 7 days ■ symptoms clear up and occur again within a few days ■ excessive skin irritation occurs ■ have redness over the affected area.

When using this product ■ avoid contact with eyes or mucous membranes ■ do not bandage tightly

Keep out of reach of children. If swallowed get medical help immediately 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 ■ ask a doctor.

Other information Store at 20° to 25°C (68° to 75°F).

Questions or information call toll free: 1-855-ATOPALM

Distributed by: NeoPharm USA, 1 Oyster Bay Drive, Rumson, NJ 07760

Made in Korea #75729

ATOPALM PAIN RELIEVING

menthol cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:51141-0239
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	10 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
GLYCERIN (UNII: PDC6A3C0OX)	
CETYL ALCOHOL (UNII: 936JST6JCN)	

POLYSORBATE 60 (UNII: CAL22UVI4M)
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)
STEARIC ACID (UNII: 4ELV7Z65AP)
DIMETHICONE (UNII: 92RU3N3Y1O)
ISOPROPYL MYRISTATE (UNII: 0RE8K4LNJS)
MYRISTOYL/PALMITOYL OXOSTEARAMIDE/ARACHAMIDE MEA (UNII: 1211AIM8G7)
TROLAMINE (UNII: 9O3K93S3TK)
CHOLESTEROL (UNII: 97C5T2UQ7J)
ALOE VERA LEAF (UNII: ZY81Z83H0X)
METHYLPARABEN (UNII: A2I8C7HI9T)
PROPYLPARABEN (UNII: Z8IX2SC1OH)

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:51141-0239-2	1 in 1 CARTON		
1		57 g in 1 TUBE		

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph not final	part348	08/14/2012		

Labeler - NeoPharm Co., Ltd. (965502912)

Establishment			
Name	Address	ID/FEI	Business Operations
NeoPharm Co., Ltd.		631101883	manufacture(51141-0239)