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

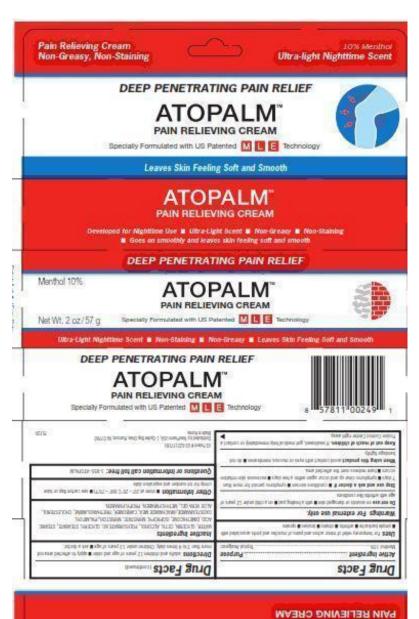
ATOPALM (TM)

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



Mon-Greasy, Non-Staining



MJA9OTA Ultra-light Mighttime Scent

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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

TOPICAL Route of Administration

Active Ingredient/Active Moiety

Ingredient Name		Basis of Strength	Strength
	MENTHOL (UNII: L7T10 EIP3A) (MENTHOL - UNII:L7T10 EIP3A)	MENTHOL	10 g in 100 g

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

POLYSORBATE 60 (UNII: CAL22UVI4M)	
GLYCERYL MONOSTEARATE (UNII: 230 O U9 XXE4)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
DIMETHICO NE (UNII: 92RU3N3Y1O)	
ISOPROPYL MYRISTATE (UNII: 0 RE8 K4LNJS)	
MYRISTO YL/PALMITO YL O XO STEARAMIDE/ARACHAMIDE MEA (UNII: 1211AIM8 G7)	
TROLAMINE (UNII: 903K93S3TK)	
CHOLESTEROL (UNII: 97C5T2UQ7J)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
METHYLPARABEN (UNII: A218 C7HI9 T)	
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	
Neo Pharm Co., Ltd.		631101883	manufacture(51141-0239)	

Revised: 8/2012 NeoPharm Co., Ltd.