MUSCLE AND JOINT - menthol gel
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.

Drug Facts

Active ingredient

Menthol 2.5%

Uses

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

- simple backache
- arthritis
- strains
- bruises
- sprains

For external use only

Do not use

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

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

- 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

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

camphor, carbomer 940, glycerin, isoprophyl alcohol, methylparaben, polysorbate 60, purified water, and trolamine

Package label

Muscle and joint pain relief rub

Purpose

Topical analgesic

MUSCLE AND JOINT

menthol gel

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:51141-0005
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
Menthol (UNII: L7T10EIP3A) (Menthol - UNII:L7T10EIP3A)	Menthol	2.5 g in 100 g

Inactive Ingredients	
Ingredient Name	**Strength**
CAMPHOR (SYNTHETIC) (UNII: 5TJD82A1ET)	
CARBOMER HOMOPOLYMER TYPE C (UNII: 4Q93RCW27E)	
glycerin (UNII: PDC6A3C0OX)	
isopropyl alcohol (UNII: ND2M416302)	
methylparaben (UNII: A2I8C7HI9T)	
polysorbate 60 (UNII: CAL22UVI4M)	
water (UNII: 059QF0KO0R)	
trolamine (UNII: 9O3K93S3TK)	

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:51141-0005-4	1 in 1 BOX		
1		113 g in 1 TUBE		
2	NDC:51141-0005-2	1 in 1 BOX		
2		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	08/27/2010	

Labeler - NeoPharm Co., Ltd. (631101883)

Registrant - NeoPharm Co., Ltd. (631101883)

Establishment

Name	Address	ID/FEI	Business Operations
NeoPharm Co., Ltd.		631101883	manufacture

Revised: 8/2010

NeoPharm Co., Ltd.