MUSCLE RUB ULTRA - camphor, menthol, methyl salicylate 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.

Drug Facts

Active Ingredients

Camphor 4%

Menthol 10%

Methyl Salicylate 30%

Uses

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

- simple bachache
- arthritis
- strains
- bruises
- sprains

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

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 to avoid accidental ingestion.

If swallowed, get medical help or contact a Poison Control Center immediately

Directions

- Use only as directed
- 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

carbomer, edetate disodium, glyceryl stearate se, lanolin, polysorbate 80, potassium hydroxide, purified water, stearic acid, trolamine

Questions?

call 1-800-883-0085, weekdays, 9AM -5PM PST Muscle Rub Ultra

MUSCLE RUB ULTRA STRENGTH



Topical analgesic Topical analgesic Topical analgesic

MUSCLE RUB ULTRA

camphor, menthol, methyl salicylate cream

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:51141-0659
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	
Menthyl Salicylate (UNII: 43XOA705ZD) (Menthyl Salicylate - UNII:43XOA705ZD)	Menthyl Salicylate	30 g in 100 g	
Camphor (Natural) (UNII: N20HL7Q941) (Camphor (Natural) - UNII:N20HL7Q941)	Camphor (Natural)	4 g in 100 g	

Inactive Ingredients		
Ingredient Name	Strength	
EDETATE DISO DIUM (UNII: 7FLD9 1C86K)		
GLYCERYL MONOSTEARATE (UNII: 230 O U9 XXE4)		
LANOLIN (UNII: 7EV65EAW6H)		
POLYSORBATE 80 (UNII: 6OZP39ZG8H)		
POTASSIUM HYDROXIDE (UNII: WZH3C48M4T)		
STEARIC ACID (UNII: 4ELV7Z65AP)		
TROLAMINE (UNII: 903K93S3TK)		
WATER (UNII: 059QF0KO0R)		

Packaging			
# Item Cod	le Package Description	Marketing Start Date	Marketing End Date
1 NDC:51141-0659-	4 1 in 1 BOX		
1	113 g in 1 TUBE		
2 NDC:51141-0659-	1 in 1 BOX		
2	65 g in 1 TUBE		

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	08/16/2010	

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.