

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 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

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, isopropyl alcohol, methylparaben, polysorbate 60, purified water, and trolamine

Package label

Muscle and joint pain relief rub

VANISHING SCENT



FAST
MUSCLE & JOINT
PAIN RELIEF

Relevación rápida del dolor de menor importancia de la artritis, del dolor de espalda, del músculo y del empalme.

NDC No. 51141-0059-2
Pure-Aid™

Compare to penetrating pain relief BENGAY® active ingredient*

- Fast Muscle & Joint Pain Relief
- Penetrating Muscle Relaxation

KAREWAY

VANISHING SCENT

Muscle & Joint Pain Relief Rub

Non-Greasy Pain Relieving Gel

NET 2 oz (57g)

Muscle & Joint Pain Relief Rub

Non-Greasy Pain Relieving Gel



8 56023 00059 2

Muscle & Joint Pain Relief Rub
Non-Greasy Pain Relieving Gel

LOT & EXP.

<p>Drug Facts (continued)</p> <ul style="list-style-type: none"> ■ symptoms clear up and occur again within a few days ■ excessive skin irritation occurs <p>Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center immediately.</p> <p>Directions</p> <ul style="list-style-type: none"> ■ 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 <p>Other information ■ store at 20° to 25° C (68° to 77° F)</p> <p>Inactive ingredients ■ camphor, carbomer 940, glycerin, isopropyl alcohol, methylparaben, polysorbate 60, purified water, and trolamine</p> <p><small>*This product is not manufactured or distributed by PFIZER CONSUMER HEALTHCARE, owner of the registered trademark BENGAY®.</small></p> <p><small>Exclusively distributed by : Kareway Product Inc. Compton, CA 90220</small></p> <p><small>Made in Korea</small></p>	<p>Drug Facts</p> <p>Active ingredients (in each gram) Purpose Menthol 2.5%.....Topical analgesic</p> <p>Uses temporarily relieves the minor aches and pains of muscles and joints associated with: ■ simple backache ■ arthritis ■ strains ■ bruises ■ sprains</p> <p>Warnings For external use only</p> <p>Do not use</p> <ul style="list-style-type: none"> ■ on wounds or damaged skin ■ with a heating pad ■ on a child under 12 years of age with arthritis-like conditions <p>Ask a doctor before use if you have redness over the affected area.</p> <p>When using this product ■ avoid contact with eyes or mucous membranes ■ do not bandage tightly</p> <p>Stop use and ask a doctor if ■ condition worsens or symptoms persist for more than 7 days</p>
---	---

Muscle & Joint Pain Relief Rub
Non-Greasy Pain Relieving Gel

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: A218C7H9T)	
polysorbate 60 (UNII: CAL22UVI4M)	
water (UNII: 059QF0K00R)	
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.