# MUSCLE RUB ULTRA STRENGTH PAIN RELIEVING- menthol cream Personal Care Products, Inc.

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.

-----

# **Active Ingredient**

# **Drug Facts**

Menthol 2.5%

# **Purpose**

Topical analgesic

# Keep out of reach of children

**Keep out of reach of children to avoid accidental ingestion.** If swallowed, get medical help or contact a Poison Control Center immediately.

### Uses

Temporarily relieves the 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

- 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 mucus membranes
- do not bandage tightly

Stop use and ask a doctor if

- condition worsens or symptoms persist for more than 7 days
- excessive skin irritation occurs
- symptoms clear up and occur again within a few days

# **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 between 59° and 86° F (15° and 30° C)
- close cap tightly after use
- do not use if seal on tube is punctured or missing

# **Inactive ingredients**

camphor, carbomer, DMDM hydantoin, PEG-40 hydrogenated castor oil, isopropyl alcohol, stearic acid, glyceryl monostearate, purified water, sodium hydroxide.

**Product Label** 

**DRUGSTORE-Rx** 

**SMART WELLNESS** 

**Ultra Strength** 

Muscle Rub

# **Pain Relieving Cream Analgesic**

Relieves minor

- Arthritis
- Backache
- Muscle pain
- Joint pain

Fast penetrating

Long lasting

NET WT. 1.5 OZ. (42 g)

**DRUGSTORE-Rx** 

SMART WELLNESS delivers outstanding quality in healthcare products, at truly amazing prices. We employ the highest standard when searching the world to bring the best value to your doorstep. Use our products confidently, knowing that attention and care has gone into every item. That's smart wellness!

Distributed by: PERSONAL CARE PRODUCTS, LLC Troy, Michigan 48084 U.S.A.

Code No. MH/DRUGS/KD-313

Made in India

DRUGSTORE-RX WELLNESS

> Pain Relieving Cream Muscle Rub

Backache · Muscle pain

Joint pain

Relieves minor · Arthritis

Ultra Strength

GSTORE-R

# Ultra Strength Muscle Rub Pain Relieving Cream

Analgesic

Relieves minor

- · Arthritis
- Backache
- Muscle pain
- · Joint pain

Fast penetrating

Long Lasting

# DRUGSTORE-RX

that attention and care has gone into every item. to bring the best value to your doorstep. Use our products confidently, knowing truly amazing prices. We employ the highest standard when searching the world SMART WELLNESS delivers outstanding quality in healthcare products, at That's smart wellness!

Troy, Michigan 48084 U.S.A. Distributed by: PERSONAL CARE PRODUCTS, LLC

Code No.: MH/DRUGS/KD-313



Made in India



# NET WT. 1.5 OZ. (42 g)



# Drug Facts Active ingredients Perpose Menthol 2,50% Topical analyseic USES Temporarily relieves the milnor aches and pairs of muscles and joints associated with: \*\*\*simple beckacke \*\*\* arthritis \*\*\* strains \*\*\* bruisses \*\*\* speairs Warnings For external use only Do not use \*\*\* on wounds or damaged skin \*\*\* with a heating goal \*\*\* on a child under 12 years of age with arthritis-like conditions Ack a doctor before use if you have reclasss over the affected area When asing this product \*\*\* avoid contact with eyes or muscous membranes \*\*\* do not bankage lightly \*\*\*

# Drug Facts continued

Slop use and set a dector if so condition worsers or symptoms pensist for more than 7 days so excessive skin inflation occurs so symptoms clear up and occur again within a few days

Keep est of reach of children to avaid accidental inspection. 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 between 59' and 86' F (15' and 30' C) close cap tightly after use do not use if seal on tube is paratured or missing

Inactive ingredients camphor, carborner, DMDM hydantoin, PEG 40 hydrogenated caster oil, isopropyl alcohol, stearic acid, glyceryl monostearate, purified vester, sodium hydrodde.

# MUSCLE RUB ULTRA STRENGTH PAIN RELIEVING

menthol cream

# **Product Information**

Product TypeHUMAN OTC DRUGItem Code (Source)NDC:29500-2433

Route of Administration TOPICAL

GLYCERYL MONOSTEARATE (UNII: 230 O U9 XXE4)

# **Active Ingredient/Active Moiety**

Ingredient NameBasis of StrengthStrengthMENTHOL (UNII: L7T10 EIP3A) (MENTHOL - UNII:L7T10 EIP3A)MENTHOL1.05 g in 42 g

# Inactive Ingredients Ingredient Name Strength CAMPHOR (NATURAL) (UNII: N20HL7Q941) CARBOMER HOMOPOLYMER TYPE C (ALLYL PENTAERYTHRITOL CROSSLINKED) (UNII: 4Q93RCW27E) DMDM HYDANTO IN (UNII: BYR0546TOW) POLYOXYL 40 HYDROGENATED CASTOR OIL (UNII: 7YC686GQ8F) ISOPROPYL ALCOHOL (UNII: ND2M416302) STEARIC ACID (UNII: 4ELV7Z65AP) WATER (UNII: 059QF0KO0R) SODIUM HYDROXIDE (UNII: 55X04QC32I)

Packaging								
#	Item Code	Package Description	Marketing Start Date	Marketing End Date				
1	NDC:29500-2433-1	42 g in 1 TUBE						

Marketing Information							
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date				
OTC monograph not final	part348	07/10/2013					

# Labeler - Personal Care Products, Inc. (966155082)

# Registrant - Personal Care Products, Inc. (966155082)

Establishment								
Name	Address	ID/FEI	Business Operations					
Anicare Pharmaceuticals Pvt. Ltd.		916837425	manufacture(29500-2433)					

Revised: 7/2013 Personal Care Products, Inc.