

BUDPACK MUSCLE RUB- menthol gel

Budpack 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.

Drug Facts

Active Ingredients

Menthol 2.5%

Purpose

Topical Analgesic

Uses ▪ Provides soothing relief of minor arthritis pain, aching muscles, joints and backache.

Warnings

- Avoid contact with eyes or mucous membranes. ▪ Discontinue use if excessive irritation of the skin develops. ▪ Do not bandage tightly, apply to wounds, broken or irritated skin, or use with a heating pad. ▪ If condition worsens, or if symptoms persist for more than 10 days or clear-up and occur again within a few days, if skin redness or irritation develops, discontinue use of this product and consult a doctor. For arthritis like conditions in children under 12, do not use. Consult a doctor.
- For external use only. Use only as directed. Keep out of the reach of children to avoid accidental poisoning.
- If swallowed, get medical help 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 3-4 times daily and gently massage until gel disappears. ▪ Children under 12 years of age: do not use, consult a doctor

Other Information

- Store at controlled room temperature 15 to 30C (59 to 86F) ▪ Lot No. Exp. Date: see box or see crimp of tube.

Inactive Ingredients Camphor, Carbomer, DMDM Hydantoin, Isoceteth, Isopropyl Alcohol, PEG-40 Hydrogenated Castor Oil, Sodium Hydroxide and Water

Package Label

Budpak

*Compare to the active ingredients of Ben-Gay® Vanishing Scent

EXTRA STRENGTH MUSCLE RUB

FAST PENETRATING RELIEF OF MUSCLE ACHES & ARTHRITIS PAIN

EXTRA POTENTE

UNTADURA MUSCULAR

GEL ALIVIADORA DE DOLOR

EXTRA STRENGTH MUSCLE RUB

NET WT 1.25 OZ (35g)

NON-GREASY PAIN RELIEVING GEL

EXTRA STRENGTH MUSCLE RUB

PAIN RELIEVER GEL



This product is not manufactured or distributed by Pfizer Consumer Health Care, owner of the trademark Bengay®.
Distributed by BUDPAK INC., Ronkonkoma, NY 11779
Made in China

Sodium Hydroxide, Water.

Inactive Ingredients Camphor, Carbomer, DMDM Hydantoin, Isobutyl Alcohol, PEG-40 Hydrogenated Castor Oil.

Other information ■ Store at controlled room temperature 15 to 30°C (59 to 85°F) ■ Lot No. & Exp. Date: see box or see crimped tube.

■ Admits and children 12 years of age and older: apply to the affected area not more than 3 to 4 times daily and gently massage until gel disappears. ■ Children under 12 years of age: do not use, consult a doctor.

Directions

■ For adults and children 12 years of age and older: apply to the affected area not more than 3 to 4 times daily and gently massage until gel disappears. ■ Children under 12 years of age: do not use, consult a doctor.

■ For arthritis like condition in children under 12, do not use. Consult a doctor.

■ If skin redness or irritation develops, discontinue use of this product and consult a doctor.

■ If condition worsens, or if symptoms persist for more than 10 days or clear-up and occur again within a few days, do not bandage tightly; apply to wounds, broken or irritated skin, or use with a heating pad.

■ Avoid contact with eyes or mucous membranes. ■ Discontinue use if excessive irritation of the skin develops.

Warnings

■ Provides soothing relief of minor arthritis pain, aching muscles, joints and backaches.

Uses

Menthol - 25%
Topical Analgesic

Active ingredients

Purpose

Drug Facts

**EXTRA STRENGTH
MUSCLE RUB**

Budpak

Budpak
EXTRA STRENGTH
MUSCLE RUB
NON-GREASY PAIN
RELIEVING GEL

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EXTRA STRENGTH
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BUDPACK MUSCLE RUB

menthol gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:27293-030
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)	
DMDM HYDANTOIN (UNII: BYR0546TOW)	
ISOPROPYL ALCOHOL (UNII: ND2M416302)	
POLYOXYL 40 HYDROGENATED CASTOR OIL (UNII: 7YC686GQ8F)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
WATER (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:27293-030-35	35 g in 1 TUBE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	06/30/2012	

Labeler - Budpack Inc. (183224849)

Establishment

Name	Address	ID/FEI	Business Operations
Ausmetics Daily Chemicals (Guangzhou) Co. Ltd.		529836561	manufacture

Revised: 6/2012

Budpack Inc.