MAKESENSE EXTRA STRENGTH MUSCLE RUB- menthol gel Cherry Hill Sales Co

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

- temporarily relieves the minor arthritis pains of muscles and joints associated with simple backache
- bruises ■arthritis ■strains ■sprains

Warnings

For external use only. Flammable: Keep away from fire or flame

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 ■ you have redness over the affected area

Keep out of reach of children

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

Directions

- adults and children12 years of age and older: apply to affected area not more than 3-4 times
- children under 12 years of age: ask a doctor

Other information

■ store at room temperature 20 to 25C (68 to 77F)

Inactive Ingredients

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

Package Label



MAKESENSE EXTRA STRENGTH MUSCLE RUB

menthol gel

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:69020-200
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 HYDANTO IN (UNII: BYR0546 TOW)		
ISOPROPYL ALCOHOL (UNII: ND2M416302)		
POLYOXYL 40 HYDROGENATED CASTOR OIL (UNII: 7YC686GQ8F)		
SO DIUM HYDRO XIDE (UNII: 55X04QC32I)		
WATER (UNII: 059QF0KO0R)		

Packaging			
# Item Code	Package Description	Marketing Start Date	Marketing End Date
1 NDC:69020-200-15	42.5 g in 1 TUBE		

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	06/01/2014	

Labeler - Cherry Hill Sales Co (145959768)

Establishment			
Name	Address	ID/FEI	Business Operations
Ausmetics Daily Chemicals (Guangzhou) Co. Ltd.		529836561	manufacture(69020-200)

Revised: 6/2014 Cherry Hill Sales Co