

ULTRA STRENGHT MUSCLE RUB- methyl salicylate, menthol cream
Inspec Solutions LLC.

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.

Ultra Strength Muscle Rub

Active ingredient

Menthol - 8.00%

Methyl Salicylate - 30.00%

Purpose

Menthol - 8.00% External Analgesic

Methyl Salicylate - 30.00% External Analgesic

Uses Temporary relief for minor aches and pains of muscles and joints.

Warnings

For external use only, Do not bandage tightly, apply to wounds or damaged skin or use with a heating pad.

Caution: Discontinue use if excessive irritation of skin develops, Avoid getting into eyes or mucous membranes, If condition worsens, or symptoms persist for more than 7 days or clear up and occur again within few days, or redness is present, or in conditions affecting children under 12 years of age, discontinue use and consult a physician immediately.

Keep out of reach of children to avoid accidental poisoning, if swallowed, get medical help or contact a poison control center right away.

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.

DEA-Cetyl Phosphate

Glyceryl Stearate

Lanolin

Potassium Stearate

Stearic Acid

Water

ULTRA STRENGTH

Muscle Rub

DEEP PENETRATING PAIN RELIEF

Helps Relieve Pain Associated with Arthritis Pain, Backache, Muscle and Joint Pain

NET WT 4 FL OZ (113 g)

Drug Facts

Active ingredients: Methyl Salicylate - 30%, Menthol - 8%..... **Purpose:** External Analgesic

Uses: For the temporary relief of minor aches and pains of muscles and joints.

Warnings: • For external use only. • Keep out of reach of children to avoid accidental poisoning. • If swallowed, get medical help or contact a Poison Control Center right away. • Do not bandage tightly, apply to wounds or damaged skin or use with a heating pad. **Caution:** Discontinue use if excessive irritation of the skin develops. • Avoid getting into eyes or mucous membranes. • If condition worsens, or symptoms persist for more than 7 days or clear up and occur again within a few days, or redness is present, or in conditions affecting children under 12 years of age, discontinue use and consult a physician 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: Consult a doctor.

Other information: • Store at controlled room temperature 15°-30°C (59°-86°F). • Close cap tightly after use.

Inactive ingredients: DEA-Cetyl Phosphate, Glyceryl Stearate, Lanolin, Potassium Stearate, Stearic Acid, Water.

Questions or comments? 1-888-793-8450

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ULTRA STRENGHT MUSCLE RUB

methyl salicylate, menthol cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:72667-010
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
MENTHOL, UNSPECIFIED FORM (UNII: L7T10EIP3A) (MENTHOL, UNSPECIFIED FORM - UNII:L7T10EIP3A)	MENTHOL, UNSPECIFIED FORM	8 g in 100 mL
METHYL SALICYLATE (UNII: LAV5U5022Y) (SALICYLIC ACID - UNII:O414PZ4LPZ)	METHYL SALICYLATE	30 g in 100 mL

Inactive Ingredients

Ingredient Name	Strength
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	
POTASSIUM STEARATE (UNII: 17V812XK50)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
CETYL PHOSPHATE (UNII: VT07D6X67O)	
WATER (UNII: 059QF0K00R)	
LANOLIN (UNII: 7EV65EAW6H)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:72667-010-01	113 mL in 1 TUBE; Type 0: Not a Combination Product	05/07/2019	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	05/07/2019	

Labeler - Inspec Solutions LLC. (081030372)

Establishment

Name	Address	ID/FEI	Business Operations
Inspec Solutions LLC.		081030372	manufacture(72667-010)