

MUSCLE RUB ULTRA STRENGTH- menthol and methyl salicylate cream
Natureplex 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.

Muscle Rub Ultra Strength
Topical Analgesic

Drug Facts

<i>Active ingredients</i>	<i>Purpose</i>
Menthol 1%	Topical analgesic
Methyl salicylate 15%	Topical analgesic

Use

Temporarily relieves minor aches and pains in muscles and joints associated with:

- simple backache
- arthritis
- strains
- bruises
- sprains

Warnings

For external use only.

Do not use

- on wounds or damaged skin
- with a heating pad
- on a child under 12 years old with arthritis-like conditions
- if seal on tube is punctured or missing

Stop use and ask a doctor if

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

Ask a doctor before use

- if the affected area is red
- if pregnant or breast-feeding
- for children under 2 years old
- for children up to 12 years old if prone to allergic reaction from or if sensitive to aspirin or salicylate

When using this product

- do not bandage or wrap tightly
- avoid contact with eyes or mucous membranes

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away: 800-222-1222.

Directions

- use only as directed
- adults and children 12 years old and older: apply to affected area up to 4 times daily
- children under 12 years old: ask a doctor

Other information

- store at 15 to 30°C (59 to 86°F)
- close cap tightly after use

Inactive ingredients

Carbomer, cetaryl alcohol and polysorbate 60, cetyl alcohol, glycerin, methylparaben, mineral oil, propylene glycol, propylparaben, purified water, triethanolamine

Questions or comments?

866-323-0107 or www.natureplex.com

PRINCIPAL DISPLAY PANEL - 42.5 g Tube Carton

Natureplex™

Ultra Strength

MuscleRub

For Minor Arthritis, Backache, Muscle & Joint Pain

NET WT. 1.5 Oz.

(42.5g)

menthol and methyl salicylate cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:67234-002
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	0.01 mg in 1 g
METHYL SALICYLATE (UNII: LAV5U5022Y) (SALICYLIC ACID - UNII:O414PZ4LPZ)	METHYL SALICYLATE	0.15 mg in 1 g

Inactive Ingredients

Ingredient Name	Strength
CARBOMER HOMO POLYMER TYPE C (ALLYL PENTAERYTHRITOL CROSSLINKED) (UNII: 4Q93RCW27E)	
CETYL ALCOHOL (UNII: 936JST6JCN)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128MIS)	
POLYSORBATE 60 (UNII: CAL22UVI4M)	
GLYCERIN (UNII: PDC6A3C0OX)	
METHYL PARABEN (UNII: A2I8C7HI9T)	
MINERAL OIL (UNII: T5L8T28FGP)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
PROPYL PARABEN (UNII: Z8IX2SC1OH)	
TROLAMINE (UNII: 9O3K93S3TK)	
WATER (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:67234-002-01	1 in 1 BOX	01/02/2007	
1		42 g in 1 TUBE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH NOT FINAL	part348	01/02/2007	

Labeler - Natureplex LLC (062808196)

Establishment

Name	Address	ID/FEI	Business Operations
Natureplex LLC		062808196	MANUFACTURE(67234-002)