

PROPLEX GREASELESS MUSCLE RUB- menthol, unspecified form 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.

PROPLEX GREASELESS MUSCLE RUB

Drug Facts

Active ingredients

Menthol 10%

Methyl salicylate 15%

Purposes

Topical Analgesic

Topical Analgesic

Use

Temporarily relieves minor aches and pains of muscles and joints

Warnings

For external use only.

Avoid contact with eyes and mucus membranes.

Not for prolonged use.

Do not use

- than otherwise directed
- on wounds or damaged skin
- a bandage tightly

Stop use and ask a physician if

- rash or excessive irritation of the skin develops
- condition worsens or symptoms persist for more than 7 days
- condition clears up and occurs again within a few days

If pregnant or breast-feeding, ask a health professional before use.

Keep out of reach of children.

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

Directions

Adults and children 2 years of age and older:

- apply to affected area 3 to 4 times daily

Children under 2 years of age:

- consult a physician

Other information

- store at 15 to 30°C (59 to 86°F)
- close cap tightly after use
- **Tamper Evident:** DO NOT USE IF SEAL ON TUBE IS PUNCTURED OR MISSING.

Inactive ingredients

carbomer, cetyl alcohol, glycerin, glyceryl stearate, isopropyl palmitate, methylparaben, potassium cetyl phosphate, propylparaben, purified water, stearic acid, stearyl alcohol, triethanolamine

Questions or comments?

866-323-0107 or www.natureplex.com

PRINCIPAL DISPLAY PANEL - 85 g Tube Carton

NDC # 67234-043-01

greaseless

muscle

rub

menthol 10%

methyl salicylate 15%

- Temporarily relieves minor aches and pains associated with:
 - simple backache
 - arthritis
 - muscle strains
 - bruises

NET WT. 3 oz (85 g)

PRO PLEX



greaseless
muscle rub

3109B
V 01

NDC # 67234-043-01

Provides
Penetrating
Pain
Relief.

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Manufacturer
NATUREPLEX, Olive Branch, MS 38654
1-866-323-0107



MADE IN THE USA

PROPLEX GREASELESS MUSCLE RUB

menthol, unspecified form and methyl salicylate cream

Product Information

| | | | |
|-------------------------|----------------|--------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:67234-043 |
| 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 | 10 mg in 1 g |
| METHYL SALICYLATE (UNII: LAV5U5022Y) (SALICYLIC ACID - UNII:O414PZ4LPZ) | METHYL SALICYLATE | 15 mg in 1 g |

Inactive Ingredients

| Ingredient Name | Strength |
|--|----------|
| CARBOMER COPOLYMER TYPE A (ALLYL PENTAERYTHRITOL CROSSLINKED) (UNII: 71DD5V995L) | |
| CETYL ALCOHOL (UNII: 936JST6JCN) | |
| GLYCERIN (UNII: PDC6A3C0OX) | |
| GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4) | |
| ISOPROPYL PALMITATE (UNII: 8CRQ2TH63M) | |
| METHYL PARABEN (UNII: A2I8C7HI9T) | |
| POTASSIUM (UNII: RWP5GA015D) | |
| CETYL PHOSPHATE (UNII: VT07D6X67O) | |
| PROPYL PARABEN (UNII: Z8IX2SC1OH) | |
| WATER (UNII: 059QF0KO0R) | |
| STEARIC ACID (UNII: 4ELV7Z65AP) | |
| STEARYL ALCOHOL (UNII: 2KR89I4H1Y) | |
| TROLAMINE (UNII: 9O3K93S3TK) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|---|----------------------|--------------------|
| 1 | NDC:67234-043-01 | 1 in 1 CARTON | 03/18/2019 | |
| 1 | | 85 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 | 03/18/2019 | |

Labeler - Natureplex LLC (062808196)

Establishment

| Name | Address | ID/FEI | Business Operations |
|----------------|---------|-----------|------------------------|
| Natureplex LLC | | 062808196 | MANUFACTURE(67234-043) |

