ASSURED MUSCLE RUB- menthol gel Greenbrier International, 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.

AssuredTM Muscle Rub

Drug Facts

Active ingredient

Menthol 2.5%

Purpose

Topical Analgesic

Use

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

- simple backache
- arthritis
- strains
- bruises
- sprains

Warnings

For external use only.

Avoid contact with the eyes or on mucous membranes.

Do not use

• on wounds or damaged skin

Stop use if

excessive irritation develops

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

When using this product

• do not bandage or wrap tightly

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 up to 3 to 4 times daily.

• Children under 2 years of age: consult a doctor

Other information

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

Inactive ingredients

Camphor, carbomer, DMDM hydantoin, isoceteth-20, isopropyl alcohol, PEG-40 hydrogenated castor oil, purified water, sodium hydroxide

Questions or comments?

866-323-0107 or www.natureplex.com

DISTRIBUTED BY GREENBRIER INTERNATIONAL, INC. 500 VOLVO PARKWAY CHESAPEAKE, VA 23320

PRINCIPAL DISPLAY PANEL - 42.5 g Tube Carton

ASSUREDTM

EXTRA STRENGTH PAIN RELIEVING GEL

Muscle Rub

Menthol 2.5%

Fast relief from:

- Arthritis pain
- Backache
- Muscle pain
- Joint pain

NET WT 1.5 OZ (42.5 g)



ASSURED MUSCLE RUB

| nenthol gel | | | | | | | | | | |
|---|------------------------------|--|---|--|--------------|------------|-------------------|--|--|--|
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| Product Inform | ation | | | | | | | | | |
| Product T ype | | HUMAN OTC DRUG | HUMAN OTC DRUG Item Code (Source) NDC:3 | | | | | | | |
| Route of Administ | te of Administration TOPICAL | | | | | | | | | |
| | | | | | | | | | | |
| Active Ingredie | nt/Act | tive Moiety | | | | | | | | |
| Ingredient Name Basis of Stren | | | | | | | Strengt | | | |
| MENTHOL, UNSPECIFIED FORM (UNII: L7T10EIP3A) (MENTHOL, UNSPECIFIED FORM - UNII:L7T10EIP3A) MENTHOL, UNSPECIFIED FORM - FORM | | | | | | NSPECIFIED | 2.5 g in 100 g | | | |
| Inactive Ingred | ients | | | | | | trength | | | |
| Ingredient Name | | | | | | | | | | |
| CAMPHOR (SYNTHETIC) (UNII: 5TJD82A1ET) | | | | | | | | | | |
| DMDM HYDANTO IN (UNII: BYR0546 TOW) | | | | | | | | | | |
| ISOPROPYL ALCO | HO L (U | JNII: ND2M416302) | | | | | | | | |
| POLYOXYL 40 HY | OROGE | NATED CASTOR OIL (UNII: 7YC686G | Q8F) | | | | | | | |
| SO DIUM HYDRO XI | DE (UN | II: 55X04QC32I) | | | | | | | | |
| WATER (UNII: 059Q | F0KO0 | R) | | | | | | | | |
| | | | | | | | | | | |
| | | | | | | | | | | |
| Packaging | | | | | | | | | | |
| # Item Code | | Package Description | | Marketing | g Start Date | Marketing | g End Date | | | |
| 1 NDC:33992-1136-3 | 42.5 | g in 1 TUBE; Type 0: Not a Combination | Product | 05/15/2012 | | | | | | |
| | | | | | | | | | | |
| | | | | | | | | | | |
| Marketing In | forn | nation | | | | | | | | |
| Marketing Categ | ory | Application Number or Monograph | h Citation | Marketing Start Date Marketing End Dat | | | | | | |
| OTC monograph not | final | part348 | | 05/15/2012 | 2 | | | | | |
| | | | | | | | | | | |

Labeler - Greenbrier International, Inc. (610322518)

| Establishment | | | | | | | | |
|----------------|---------|-----------|-------------------------|--|--|--|--|--|
| Name | Address | ID/FEI | Business Operations | | | | | |
| Natureplex LLC | | 062808196 | MANUFACTURE(33992-1136) | | | | | |

Revised: 12/2017

Greenbrier International, Inc.