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										
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.