NATUREPLEX EXTRA STRENGTH MUSCLE RUB- menthol, unspecified form 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.

NATUREPLEXTM EXTRA STRENGTH MUSCLE RUB

Drug Facts

Active ingredient

Menthol 2.5%

Purpose

Topical analgesic

Use

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

- simple backache
- arthritis
- strains
- bruises
- sprains

Warnings

For external use only.

Avoid contact with eyes and mucous membranes.

Do not use

• on wounds or damaged skin

When using this product

do not bandage tightly

Stop use and ask a doctor if

- excessive irritation develops
- condition worsens or symptoms persist for more than 7 days
- symptoms clear up and occur 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 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

PRINCIPAL DISPLAY PANEL - 42.5 g Tube Carton

FAST PENETRATING

PAIN RELIEF FROM:

- Arthritis pain
- Backache
- Muscle pain
- Joint pain



Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:67234-076	
Route of Administration	TOPICAL			

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
MENTHOL, UNSPECIFIED FORM (UNII: L7T10 EIP3A) (MENTHOL, UNSPECIFIED FORM UNII:L7T10 EIP3A)	- MENTHOL, UNSPECIFIED FORM	2.5 g in 100 g	

Inactive Ingredients			
Ingredient Name	Strength		
CAMPHOR (SYNTHETIC) (UNII: 5TJD82A1ET)			
CARBO MER HO MO PO L YMER, UNSPECIFIED TYPE (UNII: 0 A5MM30 7FC)			
DMDM HYDANTO IN (UNII: BYR0546 TOW)			
ISOCETETH-20 (UNII: O020065R7Z)			
ISOPROPYL ALCOHOL (UNII: ND2M416302)			
POLYOXYL 40 HYDROGENATED CASTOR OIL (UNII: 7YC686GQ8F)			
WATER (UNII: 059QF0KO0R)			

F	Packaging			
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:67234-076-01	1 in 1 CARTON	01/25/2021	
1		42.5 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	0 1/25/20 21		

Labeler - Natureplex LLC (062808196)

Establishment				
Name	Address	ID/FEI	Business Operations	
Natureplex LLC		062808196	MANUFACTURE(67234-076)	

Revised: 1/2021 Natureplex LLC