

DYNARUB- pain relieving cream cream
Dynarex Corporation

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.

1135 - DynaRub NDC 67777-113-50

Active Ingredient

Menthol 10%

Purpose

Topical Analgesic

Active Ingredient

Methyl Salicylate 15%

Purpose

Topical Analgesic

Uses

For the temporary relief of minor aches and pains of muscles and joints associated with simple backache, arthritis, strains, bruises, sprains

Warnings

For external use only

Do not use on

wounds or damaged skin

When using this product

- avoid contact with eyes
- do not bandage tightly

Stop use and ask a doctor if

- condition worsens
- symptoms last more than 7 days or clear up and occur again within a few days

If swallowed, get medical help or contact a Poison Control Center right away.

Directions

- Adults and children 2 years of age and older: Apply to affected area not more than 3 to 4 times daily
- Children under 2 years of age: Consult a doctor

Other Information

store at 20°-25°C (68°-77°F).

Inactive Ingredients

Allantoin, Carbomer (Ultrez 10), Cetyl Alcohol, Dimethicone, Disodium EDTA, Glycerin, Glyceryl Monostearate, Isopropyl Myristate, Methyl Paraben, Phenoxyethanol, Potassium Cetyl Phosphate, Propyl Paraben, Purified Water, Sodium Hydroxide, Stearic Acid, Titanium Dioxide, Tween 20, Vitamin E, Xanthan Gum

Label



DYNARUB

pain relieving cream cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:67777-113
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	10 g in 100 g
METHYL SALICYLATE (UNII: LAV5U5022Y) (SALICYLIC ACID - UNII:O414PZ4LPZ)	METHYL SALICYLATE	15 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
GLYCERIN (UNII: PDC6A3C0OX)	
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	
ISOPROPYL MYRISTATE (UNII: 0RE8K4LNJS)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
EDETATE DISODIUM ANHYDROUS (UNII: 8NLQ36F6MM)	
WATER (UNII: 059QF0KO0R)	
ALLANTOIN (UNII: 344S277G0Z)	
CARBOXYPOLYMETHYLENE (UNII: 0A5MM307FC)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
CETYL ALCOHOL (UNII: 936JST6JCN)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
ALPHA-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
XANTHAN GUM (UNII: TTV12P4NEE)	
POTASSIUM CETYL PHOSPHATE (UNII: 03KCY6P7UT)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
POLYSORBATE 20 (UNII: 7T1F30V5YH)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:67777-113-50	72 in 1 CASE	09/12/2016	
1	NDC:67777-113-49	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
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OTC monograph not final	part348	09/12/2016	
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Labeler - Dynarex Corporation (008124539)

Revised: 11/2022

Dynarex Corporation