

## **DYNAREX MUSCLE RUB CREAM- menthol and methyl salicylate 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.*

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### **Dynarex Muscle Rub Cream**

#### **Active Ingredient**

##### **Active Ingredient**

Menthol 10%

Methyl salicylate 15% w/w

##### **Purpose**

Topical analgesic

Topical analgesic

#### **Purpose**

Temporary relief of minor aches and pains of muscle joints associated with:

- simple backache
- arthritis
- strains
- bruises
- sprains

☐**Do not use** ☐other than directed.

#### **Indications and Usage**

##### **Uses**

Temporary relief of minor aches and pains of sore muscles and joints.

#### **Warnings**

##### **For external use only.**

- Avoid contact with the eyes or mucous membranes.
- Do not apply to wounds or damaged skin.
- Do not bandage tightly.
- Do not use with heating pad or device.

#### **Stop Use**

##### **Stop Use And Ask A Doctor If:**

- Condition worsens, or if symptoms persist for more than 7 days,
- symptoms clear up and occur again in a few days
- redness is present or excessive skin irritation develops

#### **Keep Out Of Reach Of Children**

##### **KEEP OUT OF REACH OF CHILDREN**

If accidentally ingested, get medical help or contact a Poison Control Center immediately.

## **Dosage & Administration**

### **Directions**

- Use only as directed
- Adults and children 12 years of age and older: apply to the affected areas not more than 3 or 4 times daily.
- Children under 12 years of age: Consult a physician.

### **Other Information**

Store at 20° - 25°C (68°-77°F)

### **Inactive Ingredients**

Allantoin, carbomer, cetyl alcohol, dimethicone, disodium EDTA, glycerin, glycerol monostearate, isopropyl myristate, methylparaben, phenoxyethanol, potassium cetyl phosphate, propylparaben, purified water, sodium hydroxide, stearic acid, titanium dioxide, polysorbate 20, Vitamin E, xanthan gum.

### **Principal Display panel**

1135 GV.jpg

**Drug Facts****Active Ingredients**

Menthol 10% w/w .....Topical analgesic  
 Methyl Salicylate 15% w/w.....Topical analgesic

**Purpose****Uses**

Temporarily relieves the minor aches and pains of muscles and joints associated with: ■ simple backache ■ arthritis ■ strains ■ bruises ■ sprains  
**Do not use** other than as directed

**When using this product**

■ avoid contact with the eyes or mucous membranes ■ do not apply to wounds or damaged skin ■ do not bandage tightly  
 ■ do not use with a heating pad

**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 ■ redness is present or excessive skin irritation develops

**Keep out of reach of children.**

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

**Drug Facts (continued)****Directions**

■ use only as directed ■ adults & children 12 years of age and older: apply to affected area not more than 3 to 4 times daily ■ children under 12 years of age: ask a doctor

**Other information**

■ store at 20°-25°C (68°-77°F)

**Inactive Ingredients**

Allantoin, Carbomer (Ultrez 10), Cetyl Alcohol, Dimethicone, Disodium EDTA, Glycerin,

**Drug Facts (continued)**

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

Net Wt. 3 oz. (84.7g)  
 NDC #67777-416-01

Reorder No. 1135

**DynaRub™**  
 Non-Greasy Pain Relieving Cream



LOT NUMBER AND EXPIRATION DATE IS TO BE PRINTED HERE

Manufactured for:  
 Dynarex Corporation  
 Orangeburg, NY 10962  
 www.dynarex.com  
 Made in India

**DYNAREX MUSCLE RUB CREAM**

menthol and methyl salicylate cream

**Product Information**

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:67777-416
<b>Route of Administration</b>	TOPICAL		

**Active Ingredient/Active Moiety**

Ingredient Name	Basis of Strength	Strength
MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	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
CETYL ALCOHOL (UNII: 936JST6JCN)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
POTASSIUM CETYL PHOSPHATE (UNII: 03KCY6P7UT)	
XANTHAN GUM (UNII: TTV12P4NEE)	
GLYCERIN (UNII: PDC6A3C0OX)	
CARBOMER 940 (UNII: 4Q93RCW27E)	
ALLANTOIN (UNII: 344S277G0Z)	
METHYL PARABEN (UNII: A2I8C7HI9T)	
PROPYL PARABEN (UNII: Z8IX2SC1OH)	
POLYSORBATE 20 (UNII: 7T1F30V5YH)	
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	
ISOPROPYL MYRISTATE (UNII: 0RE8K4LNJS)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
ALPHA-TOCOPHEROL (UNII: H4N855PNZ1)	
WATER (UNII: 059QF0KO0R)	

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:67777-416-01	85 g in 1 TUBE; Type 0: Not a Combination Product	05/16/2016	

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	05/16/2016	

**Labeler** - Dynarex Corporation (008124539)

**Registrant** - Dynarex Corporation (008124539)

Revised: 6/2017

Dynarex Corporation