

## **RUGBY MUSCLE RUB CREAM- muscle rub cream cream**

### **Rugby Laboratories**

*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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### **Drug Facts**

#### **Active Ingredients**

Menthol - 10%

Methyl salicylate - 15%

#### **Purpose**

Topical Analgesic

Topical Analgesic

#### **Uses**

- For temporary relief of minor aches and pains of muscle and joints associated with simple backaches, arthritis, strains, bruises and sprains

#### **Warnings**

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

##### **Avoid contact with eyes and mucous membranes**

- If conditions worsens, or if symptoms persist for more than 7 days or clear up and occur again within a few days, discontinue use of this product and consult a doctor.
- Do not apply to wounds or damaged skin.
- Do not apply bandage tightly.
- Do not use with a heating pad or on wounds, damaged, broken (open) or irritated skin.
- Discontinue use if excessive irritation of skin develops.
- If pregnant or breast feeding, ask a health professional before use.
- A temporary burning sensation may occur upon application, but generally disappears in a few days.

**Keep this and all drugs out of the reach of children.** If swallowed, get medical help or contact a Poison Control Center immediately.

#### **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.
- Unless treating hands, wash hands thoroughly with soap and water immediately after use.

### **Other information**

Store at controlled room temperature 68° - 77°F ( 20° to 25°C) Close cap tightly after use.

### **Inactive ingredients**

Carbomer, Cetyl Alcohol, Oleth-3 Phosphate, Stearic acid, Triethanolamine, Purified Water

### **Principal Display Panel - 3.0 oz Carton**

Rugby

Greaseless

MUSCLE RUB Cream

10% Menthol / 15% Methyl Salicylate

Topical Analgesic

Net WT. 3.0 OZ (85g)



## Principal Display Panel - 3.0 oz Tube

Rugby

Greaseless

MUSCLE RUB Cream

10% Menthol / 15% Methyl Salicylate

Topical Analgesic

Net WT. 3.0 OZ (85g)



NDC 0536-1349-57  
Compare to the active ingredients in Bengay\*\*

**Greaseless**  
**Muscle Rub Cream**  
10% Menthol | 15% Methyl Salicylate

**Topical Analgesic Cream**

For Fast Penetrating Relief of Muscle Aches **NET WT. 3 OZ. (85 g)**

**Active ingredients:** Menthol - 10%, 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 and sprains. **Warnings:** For external use only • Avoid contact with the eyes and mucous membranes • If condition worsens, or if symptoms persist for more than 7 days or clear up and occur again within a few days, discontinue use of this product and consult a doctor. • Do not apply to wounds or damaged skin. • Do not bandage tightly. • Do not use with a heating pad or on wounds, damaged, broken (open) or irritated skin. • Discontinue use if excessive irritation of skin develops. • If pregnant or breast feeding, ask a health professional before use. • A temporary burning sensation may occur upon application, but generally disappears in a few days. **Keep this and all drugs out of the reach of children.** If swallowed, get medical help or contact a Poison Control Center immediately 800-222-1222. **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. • Unless treating hands, wash hands thoroughly with soap and water immediately after use. **Other information:** • Store at controlled room temperature 68°-77 °F (20°-25C°) • Close the cap tightly after use. **Questions?** 1-800-645-2158 \*This product is not manufactured or distributed by Johnson & Johnson Consumer Inc., owner of the registered trademark Bengay®.

**KEEP CARTON FOR COMPLETE DRUG FACTS.**

Made in USA OF U.S. & Imported Ingredients and Components  
Distributed by: RUGBY® LABORATORIES Livonia, MI 48152  
www.rugbylaboratories.com

Rev.12/21 R-101 Re-order No. 371133  
  
3 05361 34957 08 2503012

## RUGBY MUSCLE RUB CREAM

muscle rub cream cream

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:0536-1349
<b>Route of Administration</b>	TOPICAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>MENTHOL</b> (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	100 mg in 1 g
<b>METHYL SALICYLATE</b> (UNII: LAV5U5022Y) (SALICYLIC ACID - UNII:O414PZ4LPZ)	METHYL SALICYLATE	150 mg in 1 g

### Inactive Ingredients

Ingredient Name	Strength
<b>CARBOMER 940</b> (UNII: 4Q93RCW27E)	
<b>CETYL ALCOHOL</b> (UNII: 936JST6JCN)	
<b>TROLAMINE</b> (UNII: 9O3K93S3TK)	

**WATER** (UNII: 059QF0KO0R)

**STEARIC ACID** (UNII: 4ELV7Z65AP)

**OLETH-3 PHOSPHATE** (UNII: 8Q0Z18J1VL)

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0536-1349-57	1 in 1 CARTON	02/28/2022	
1		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
OTC monograph not final	part348	02/28/2022	

**Labeler** - Rugby Laboratories (079246066)

**Registrant** - Sheffield Pharmaceuticals LLC (151177797)

### Establishment

Name	Address	ID/FEI	Business Operations
Sheffield Pharmaceuticals LLC		151177797	manufacture(0536-1349)

Revised: 2/2022

Rugby Laboratories