

RUGBY PAIN RELIEVING ANALGESIC- menthol, unspecified form and methyl salicylate cream

Rugby Laboratories

Rugby® Pain Relieving Cream Topical Analgesic

Drug Facts

Active ingredients	Purpose
Menthol 1.0%	Topical Analgesic
Methyl Salicylate 15.0%	Topical Analgesic

Use

For the temporary relief of minor aches and pains of muscles and joints associated with

- arthritis
- simple backache
- strains
- sprains

Warnings

For external use only

Do not use

- immediately after shower or bath
- with a heating pad
- on wounds, damaged, broken or irritated skin

When using this product

- use only as directed
- do not swallow
- do not bandage tightly
- avoid contact with eyes and mucous membranes

Stop and ask a doctor if

- skin redness or irritation develops
- condition worsens or pain lasts for more than 7 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.

Directions

- adults and children 12 years and over: apply to affected area not more than 3 to 4 times daily
- children under 12 years: ask a doctor.

Other information

Store at room temperature 15° - 30°C (59°F - 86°F).

Inactive ingredients

Carbomer, Cetearyl Alcohol, Dimethicone, Glycerin, Methylparaben, Polysorbate 60, Propylparaben, Sodium Hydroxide, Sodium Lauryl Sulfate, Water

Questions or comments?

1-800-645-2158

Distributed by:
Rugby Laboratories
31778 Enterprise Drive
Livonia, MI 48150

PRINCIPAL DISPLAY PANEL - 85 g Tube Carton

NDC 0536-1101-45

Rugby[®]
MAXIMUM STRENGTH

**PAIN RELIEVING
CREAM**

Net Wt 3 oz (85 g)



RUGBY PAIN RELIEVING ANALGESIC

menthol, unspecified form and methyl salicylate cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:0536-1101
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
MENTHOL, UNSPECIFIED FORM (UNII: L7T10EIP3A) (MENTHOL, UNSPECIFIED FORM - UNII:L7T10EIP3A)	MENTHOL, UNSPECIFIED FORM	10 mg in 1 g

Methyl Salicylate (UNII: LAV5U5022Y) (SALICYLIC ACID - UNII:O414PZ4LPZ)

Methyl Salicylate

150 mg
in 1 g

Inactive Ingredients

Ingredient Name	Strength
CARBOXYMETHYLCELLULOSE SODIUM, UNSPECIFIED (UNII: K679OBS311)	
Cetostearyl Alcohol (UNII: 2DMT128M1S)	
Dimethicone (UNII: 92RU3N3Y1O)	
Glycerin (UNII: PDC6A3C0OX)	
Methylparaben (UNII: A2I8C7HI9T)	
Polysorbate 60 (UNII: CAL22UVI4M)	
Propylparaben (UNII: Z8IX2SC1OH)	
Sodium Hydroxide (UNII: 55X04QC32I)	
Sodium Lauryl Sulfate (UNII: 368GB5141J)	
Water (UNII: 059QF0K00R)	

Product Characteristics

Color	white	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0536-1101-45	1 in 1 CARTON	05/11/2016	
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 Drug	M017	05/11/2016	

Labeler - Rugby Laboratories (079246066)

Registrant - Garcoa, Inc. (103039178)