

## **MUSCLE RUB- menthol, unspecified form and methyl salicylate cream Galentic Pharma (India) Private Limited**

*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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**Muscle Rub**

- **ACTIVE INGREDIENT**

Menthol 10%

Methyl Salicylate 15%

- **PURPOSE**

Topical analgesic

- **USES**

Temporarily relieves the 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
- With a heating pad
- On a child under 12 years of age with arthritis-like conditions

**Ask a doctor before use if you have**

- redness over the affected area

**When using this product**

- Avoid contact with eyes or mucous membrane
- Do not bandage tightly

**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

- Excessive skin irritation occurs
- KEEP OUT OF REACH OF CHILDREN

**Keep out of reach of children to avoid accidental ingestion.** If swallowed, get medical help or contact a Poison Control Center immediately.

- **DIRECTIONS**

- Use only as directed
- Adults and 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 15° to 25 °C (59° to 77°F)
- Lot No. & Exp. Date : See box or see crimp of tube

- **INACTIVE INGREDIENTS**

Citric Acid, Glyceryl Monostearate, Lanolin, Methylparaben, Propylene Glycol, Propylparaben, Purified Water, Polysorbate 80, Stearic Acid, Trolamine

Manufactured by : **Galentic Pharma (India) Pvt. Ltd.**, Plot No. 5-B & 5-C, Sector III, Kandla Special Economic Zone,

Gandhidham-370 230, Gujarat. India

**PRINCIPAL DISPLAY PANEL - 85 g Tube Carton**

**Galentic**

**Muscle Rub**

***ULTRA STRENGTH***

***Pain Relieving Cream***

***Non-Greasy***

NET WT.

3 OZ. (85g)



**Galentic**

NET WT.  
3 OZ. (85g)

**Muscle Rub**  
ULTRA STRENGTH

*Pain Relieving Cream  
Non-Greasy*

**Galentic**

**Muscle Rub**  
ULTRA STRENGTH

*Pain Relieving Cream  
Non-Greasy*

NET WT.  
3 OZ. (85g)

**Muscle Rub**  
ULTRA STRENGTH

Made in India NDC # 50382-015-15 GUJ/DRUGS/6/25/2134

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<p><b>Keep out of reach of children to avoid accidental ingestion. If swallowed, get medical help or contact a Poison Control Center immediately.</b></p> <p>■ symptoms clear up and occur again within a few days ■ excessive skin irritation occurs</p> <p><b>Directions</b></p> <p>■ use only as directed ■ adults and 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</p> <p><b>Other information</b> ■ store at 15° to 25°C ( 59° to 77° F) Lot No. &amp; Exp. Date: See box or see crimp of tube.</p> <p><b>Inactive ingredients</b> Propylparaben, Purified Water, Polysorbate 80, Stearic Acid, Triethanolamine</p>	<p>Methyl salicylate 15% .....Topical analgesic</p> <p><b>Uses</b> temporarily relieves the minor aches and pains of muscles and joints associated with: ■ simple backache ■ arthritis ■ strains ■ bruises ■ sprains</p> <p><b>Warnings</b> <b>For external use only.</b></p> <p><b>Do not use</b></p> <p>■ on wounds or damaged skin ■ with a heating pad ■ on a child under 12 years of age with arthritis-like conditions</p> <p><b>Ask a doctor before use if you have</b> redness over the affected area.</p> <p><b>When using this product</b></p> <p>■ avoid contact with eyes or mucous membranes ■ do not bandage tightly</p>
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■ condition worsens or symptoms persist for more than 7 days  
 Stop use and ask a doctor if

Active Ingredients  
 Menthol 10%  
 Purpose  
 Topical analgesic

Drug Facts (continued)

Drug Facts

## MUSCLE RUB

menthol, unspecified form and methyl salicylate cream

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:50382-015
<b>Route of Administration</b>	TOPICAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>MENTHOL, UNSPECIFIED FORM</b> (UNII: L7T10EIP3A) (MENTHOL, UNSPECIFIED FORM - UNII:L7T10EIP3A)	MENTHOL, UNSPECIFIED FORM	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>CITRIC ACID MONOHYDRATE</b> (UNII: 2968PHW8QP)	
<b>GLYCERYL MONOSTEARATE</b> (UNII: 230OU9XXE4)	
<b>METHYLPARABEN</b> (UNII: A2I8C7HI9T)	
<b>PROPYLPARABEN</b> (UNII: Z8IX2SC1OH)	
<b>PROPYLENE GLYCOL</b> (UNII: 6DC9Q167V3)	
<b>POLYSORBATE 80</b> (UNII: 6OZP39ZG8H)	
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>STEARIC ACID</b> (UNII: 4ELV7Z65AP)	
<b>TROLAMINE</b> (UNII: 9O3K93S3TK)	
<b>LANOLIN</b> (UNII: 7EV65EAW6H)	

### Product Characteristics

<b>Color</b>	white	<b>Score</b>	
<b>Shape</b>		<b>Size</b>	
<b>Flavor</b>		<b>Imprint Code</b>	
<b>Contains</b>			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date

<b>1</b>	NDC:50382-015-15	1 in 1 CARTON	06/01/2012	
<b>1</b>		85 g in 1 TUBE; Type 0: Not a Combination Product		
<b>Marketing Information</b>				
<b>Marketing Category</b>	<b>Application Number or Monograph Citation</b>		<b>Marketing Start Date</b>	<b>Marketing End Date</b>
OTC monograph not final	part348		06/01/2012	

**Labeler** - Galentic Pharma (India) Private Limited (915110464)

### Establishment

Name	Address	ID/FEI	Business Operations
Galentic Pharma (India) Private Limited		650970176	analysis(50382-015) , manufacture(50382-015) , pack(50382-015) , sterilize(50382-015)

Revised: 11/2022

Galentic Pharma (India) Private Limited