

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.

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

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Muscle Rub
ULTRA STRENGTH

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

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<p>Keep out of reach of children to avoid accidental ingestion. If swallowed, get medical help or contact a Poison Control Center immediately.</p> <p>■ symptoms clear up and occur again within a few days ■ excessive skin irritation occurs</p> <p>Directions</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>Other information ■ store at 15° to 25°C (59° to 77° F) Lot No. & Exp. Date: See box or see crimp of tube.</p> <p>Inactive ingredients Propylparaben, Purified Water, Polysorbate 80, Stearic Acid, Triethanolamine</p>	<p>Methyl salicylate 15% Topical analgesic</p> <p>Uses temporarily relieves the minor aches and pains of muscles and joints associated with: ■ simple backache ■ arthritis ■ strains ■ bruises ■ sprains</p> <p>Warnings For external use only.</p> <p>Do not use</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>Ask a doctor before use if you have redness over the affected area.</p> <p>When using this product</p> <p>■ avoid contact with eyes or mucous membranes ■ do not bandage tightly</p>
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Active Ingredients Menthol 10%.....	PurposeTopical analgesic
Drug Facts	Drug Facts (continued)
■ Stop use and ask a doctor if ■ condition worsens or symptoms persist for more than 7 days	

MUSCLE RUB

menthol, unspecified form and methyl salicylate cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:50382-015
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	100 mg in 1 g
METHYL SALICYLATE (UNII: LAV5U5022Y) (SALICYLIC ACID - UNII:O414PZ4LPZ)	METHYL SALICYLATE	150 mg in 1 g

Inactive Ingredients

Ingredient Name	Strength
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
WATER (UNII: 059QF0K00R)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
TROLAMINE (UNII: 9O3K93S3TK)	
LANOLIN (UNII: 7EV65EAW6H)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	
METHYLPARABEN (UNII: A2I8C7HI9T)	

Product Characteristics

Color	white	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:50382-015-15	1 in 1 CARTON	06/01/2012	

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	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) , repack(50382-015) , sterilize(50382-015)

Revised: 11/2019

Galentic Pharma (India) Private Limited