

MUSCLE AND JOINT- menthol, unspecified form gel

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 and Joint

Drug Facts

• ACTIVE INGREDIENT

Menthol 2.5%

• PURPOSE

Topical Analgesic

• USES

For the temporary relief of minor aches and pains of muscles and joints associated with simple backache, arthritis, sprains, and bruises

• WARNINGS

For External Use Only.

Do not use

- On wounds or damaged skin
- With a heating pad
- On children 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 membranes
- 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. If swallowed, get medical help or contact a Poison

Control Center immediately.

- **DIRECTIONS**

- Adults 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 between 15° to 30°C (59° to 86°F)

- **INACTIVE INGREDIENT**

Camphor, Carbomer 980, Isopropyl alcohol, Methylparaben, Polysorbate 60, Potassium Sorbate, Trolamine, Purified water

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 & Joint

VANISHING SCENT GEL

Quick Relief

NET WT.

3 OZ. (85g)



Galentic

NET WT.
3 OZ. (85g)

Muscle & Joint VANISHING SCENT GEL

*Quick Relief from Minor Arthritis,
Backache, Muscle & Joint Pain*

Galentic

Muscle & Joint VANISHING SCENT GEL

Quick Relief

NET WT.
3 OZ. (85g)

Muscle & Joint VANISHING SCENT GEL

Manufactured by : Galentic Pharma (India) Pvt. Ltd., Plot No. 5-B & 5-C, Sector III, Kanda Special Economic Zone, Gandhinagar-370 230, Gurgaon, India
Made in India NDC # 50382-016-15 6AU0RUS/5/25/2134

Drug Facts	Active Ingredient Menthol 2.5%.....Topical Analgesic
Purpose	Joints associated with simple backache, arthritis, sprains and bruises.
Warnings	For external use only.
Uses	For the temporary relief of minor aches and pains of muscles and joints associated with simple backache, arthritis, sprains and bruises.
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
Directions	Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center immediately.
Other information	■ adults 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
Inactive ingredients	Polysorbate 60, Potassium Sorbate, Triethylamine, Purified Water, Camphor, Carbomer 980, Isopropyl Alcohol, Methylparaben.
Drug Facts (continued)	

When using this product

- do not bandage tightly
- avoid contact with eyes or mucous membranes

Ask a doctor before use if you have redness over the affected area.

Do not use ■ on wounds or damaged skin ■ with a heating pad ■ on children under 12 years of age with arthritis-like conditions

MUSCLE AND JOINT

menthol, unspecified form gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:50382-016
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	25 mg in 1 g

Inactive Ingredients

Ingredient Name	Strength
CAMPHOR (SYNTHETIC) (UNII: 5TJD82A1ET)	
POLYSORBATE 60 (UNII: CAL22UVI4M)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
TROLAMINE (UNII: 9O3K93S3TK)	
CARBOMER HOMOPOLYMER TYPE C (ALLYL PENTAERYTHRITOL CROSSLINKED) (UNII: 4Q93RCW27E)	
ISOPROPYL ALCOHOL (UNII: ND2M416302)	
WATER (UNII: 059QF0KO0R)	
POTASSIUM SORBATE (UNII: 1VPU26JZZ4)	

Product Characteristics

Color	white	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:50382-016-15	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(50382-016) , manufacture(50382-016) , pack(50382-016) , sterilize(50382-016)

Revised: 11/2022

Galentic Pharma (India) Private Limited