

**GADADERM FROZEN ICE ADVANCE PAIN RELIEF- salicylic acid menthol camphor (natural) gel**

**GADAL Laboratories, Inc**

*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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**ACTIVE INGREDIENTS**

<b>Active Ingredients</b>	<b>Purpose</b>
Methyl Salicylate 10%	Topical Analgesic
Menthol 10%	Topical Analgesic
Camphor 3.1%	Topical Analgesic

**INACTIVE INGREDIENT**

Carbopol, Cetearyl Alcohol, Disodium EDTA, FD&C Blue #1, Glycerin, Hydroxypropyl Methylcellulose, Menthylparaben, Propylene Glycol, Propylparaben, Polysorbate 20, Purified Water, Stearic Acid, Sodium Hydroxide.

**KEEP OUT OF REACH OF CHILDREN**

**WARNINGS**

For the external use only. When using this product use as directed.

- Do not bandage tightly or use with heating pad. Avoid contact with eyes and mucous membranes.
- Do not apply to wounds or damaged, broken, or irritated skin.
- If severe burning sensation occurs, discontinue use immediately.
- Do not expose the area treated with product to heat or direct sunlight.
- Stop use and ask a doctor if conditions worsen, redness is present, irritation develops.

If swallowed, get medical help or contact a Poison Control Center right away. IF MEDICINE COMES IN CONTACT WITH HANDS, WASH WITH SOAP AND WATER.

**DOSAGE & ADMINISTRATION**

Adults and children 12 years of age and older; apply generously to affected area massage into painful area until thoroughly absorbed into skin. Repeat as necessary but not more than 3 to 4 times daily.

**PURPOSE**

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

**GADADERM Frozen Ice Advance Pain Relief**



## GADADERM FROZEN ICE ADVANCE PAIN RELIEF

salicylic acid menthol camphor (natural) gel

### Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:53113-362
Route of Administration	TOPICAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
METHYL SALICYLATE (UNII: LAV5U5022Y) (SALICYLIC ACID - UNII:O414PZ4LPZ)	METHYL SALICYLATE	10 in 100 g
MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	10 in 100 g
CAMPHOR (NATURAL) (UNII: N20HL7Q941) (CAMPHOR (NATURAL) - UNII:N20HL7Q941)	CAMPHOR (NATURAL)	3.1 in 100 g

### Inactive Ingredients

Ingredient Name	Strength
CARBOXYPOLYMETHYLENE (UNII: 0A5MM307FC)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128MIS)	
EDETATE DISODIUM ANHYDROUS (UNII: 8NLQ36F6MM)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
GLYCERIN (UNII: PDC6A3C0OX)	
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)	
METHYL PARABEN (UNII: A2I8C7HI9T)	
PROPYL PARABEN (UNII: Z8IX2SC1OH)	

<b>POLYSORBATE 20</b> (UNII: 7T1F30V5YH)	
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>STEARIC ACID</b> (UNII: 4ELV7Z65AP)	
<b>SODIUM HYDROXIDE</b> (UNII: 55X04QC32I)	

<b>Packaging</b>				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:53113-362-09	99 g in 1 TUBE; Type 0: Not a Combination Product	09/01/2016	

<b>Marketing Information</b>			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	09/01/2016	

**Labeler** - GADAL Laboratories, Inc (841305639)

<b>Establishment</b>			
Name	Address	ID/FEI	Business Operations
GADAL Laboratories, Inc		841305639	MANUFACTURE(53113-362)

Revised: 11/2016

GADAL Laboratories, Inc