

AMPLIFY RELIEF MM- methyl salicylate, menthol cream
International Brand Management, LLC

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.

Active Ingredients :

Methyl Salicylate.....30.00%

Menthol.....10.00%

Purpose

Topical Analgesic

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 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 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

Inactive Ingredients: Aloe Barbadosis Leaf (Aloe Vera Gel) Juice, Aqua (Deionized Water), Arnica Montana Flower Extract, Boswellia Serrata Extract, Calendula Officinalis Extract, Cannabis Sativa (Hemp) Seed Oil, Cetearyl Oliviate, Cetyl Alcohol, Chondroitin Sulfate, Gluconolactone, Glucosamine Sulfate, Glycerin, Glyceryl Stearate, Helianthus Annuus (Sunflower) Oil, Magnesium

Sulfate, Methylsulfonylmethane (MSM), Sodium Benzoate, Sodium Laurylglucosides
Hydroxypropylsulfonate, Sorbitan Olivatate, Tapioca Starch, Xanthan Gum, Zemea (Corn)
Propanediol.

3.5"x5"

<p>NDC 69837-019-01</p> <p>AMPLify Relief MM</p>  <p>Topical Pain Relief Cream (Menthol 10% / Methyl Salicylate 30%)</p> <p>4 oz / 118 g</p>	<p>Drug Facts</p> <table border="0"> <tr> <td>Active Ingredients:</td> <td>Purpose</td> </tr> <tr> <td>Methyl Salicylate.....30.00%</td> <td>Topical Analgesic</td> </tr> <tr> <td>Menthol.....10.00%</td> <td>Topical Analgesic</td> </tr> </table> <p>Inactive Ingredients: Aloe Barbadensis Leaf (Aloe Vera Gel) Juice, Aqua (Deionized Water), Arnica Montana Flower Extract, Boswellia Serata Extract, Calendula Officinalis Extract, Ceraflabe Sativa (Kemp) Seed Oil, Cetearyl Olivate, Gory Alcohol, Chondroitin Sulfate, Glucosylchondroitin, Glucosamine Sulfate, Glycerin, Glyceryl Stearate, Helianthus Annuus (Sunflower) Oil, Magnesium Sulfate, Methylsilylimethane (MSM), Sodium Benzoate, Sodium Lauryl Sulfate, Hydroxypropylsulfonate, Sorbitan Olivate, Tapioca Starch, Xanthan Gum, Zinea (Zinc) Propargylol.</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 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.</p> <p>When using this product: • avoid contact with eyes or mucous membranes • do not bandage tightly</p> <p>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 to avoid accidental ingestion. If swallowed, get medical help or contact a Poison Control Center immediately.</p> <p>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</p> <p>Distributed by: 19 & Pacific 160 Greentree Drive, Suite 101 Dover, Delaware 19904</p> <p>FOR QUESTIONS OR COMMENTS: 800-992-1190</p>	Active Ingredients:	Purpose	Methyl Salicylate.....30.00%	Topical Analgesic	Menthol.....10.00%	Topical Analgesic
Active Ingredients:	Purpose						
Methyl Salicylate.....30.00%	Topical Analgesic						
Menthol.....10.00%	Topical Analgesic						

methyl salicylate, menthol cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:69837-019
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
METHYL SALICYLATE (UNII: LAV5U5022Y) (SALICYLIC ACID - UNII:O414PZ4LPZ)	METHYL SALICYLATE	3 g in 10 g
MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	1 g in 10 g

Inactive Ingredients

Ingredient Name	Strength
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
WATER (UNII: 059QF0KO0R)	
ARNICA MONTANA FLOWER (UNII: OZ0E5Y15PZ)	
INDIAN FRANKINCENSE (UNII: 4PW41QCO2M)	
CALENDULA OFFICINALIS FLOWER (UNII: P0M7O4Y7YD)	
CANNABIS SATIVA SEED OIL (UNII: 69VJ1LPN1S)	
Cetearyl Olivat (UNII: 58B69Q84JO)	
CETYL ALCOHOL (UNII: 936JST6JCN)	
CHONDROITIN SULFATE (SHARK) (UNII: 2ZAJ1K50XH)	
GLUCONOLACTONE (UNII: WQ29KQ9POT)	
Glucosamine Sulfate (UNII: 1FW7WLR731)	
GLYCERIN (UNII: PDC6A3C0OX)	
GLYCERYL STEARATE SE (UNII: FCZ5MH785I)	
SUNFLOWER OIL (UNII: 3W1JG795Y)	
MAGNESIUM SULFATE, UNSPECIFIED FORM (UNII: DE08037SAB)	
DIMETHYL SULFONE (UNII: 9H4PO4Z4FT)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
SORBITAN OLIVATE (UNII: MDL271E3GR)	
STARCH, TAPIOCA (UNII: 24SC3U704I)	
XANTHAN GUM (UNII: TTV12P4NEE)	
PROPANEDIOL (UNII: 5965N8W85T)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69837-019-01	1 in 1 CARTON	01/17/2017	
1	NDC:69837-019-02	118 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	01/17/2017	

Labeler - International Brand Management, LLC (079794940)

Establishment

Name	Address	ID/FEI	Business Operations
International Brand Management, LLC		079794940	manufacture(69837-019)

Revised: 3/2017

International Brand Management, LLC