THERA DERM- methyl salicylate lotion
Manna Omni International Incorporated

Disclaimer: This drug has not been found by FDA to be safe and effective, and this labeling has not been approved by FDA. For further information about unapproved drugs, click here.

Thera Derm Pain Relieving Lotion

Directions:

For the temporary relief of minor arthritis pain, simple backache, muscle strains and sprains.

Clean affected Area and rub or massage area continuously until lotion has been absoprbed into the area.

Directions: clean the affected area, then apply to pain area. Rub or massage the area continuously until the lotion has been fully absorbed into the area.

Warning: for external use only

Use only as directed. Avoid contact with the eyes and mucous membranes. DO not apply to open wounds, damaged or very sensitive skin. Test on a small area before use. Do not use in combination with other external analgesic products. Do not bandage tightly or cover with any type of wrap, except clothing. If condition worsens, or persists for more than seven days, discontinue use and consult a physician.

KEEP OUT OF THE REACH OF CHILDREN

If swallowed, get medical help or contact Poison Control right away.

Active Ingredients:

Menthol, Methyl Salicylate, Peppermint Oil, Camphor.

Inactive Ingredients

Salvia Miltiorrhiza root, Carthamus Tinctorius Flower Oil, Lavender Oil, Angelica Actiloba Flowering Top, Aloe,Zingiber Cassumunar Root Oil,Angelicae Pubescens Root,Stearic Acid, Prunus Persica Flower Bud,Notopterygium Franchetii Root,Frankincense Oil, Ligusticum Sinese Subsc, Chuanxiong Root, Myrrh,nGlycerin, Vitamin E Oil,Coconut Oil.

Purpose

The Purpose of our pain relieving Lotion is to provide temporary relief of minor aches and pains, arthritiis pain, backache, muscle aches and strains.

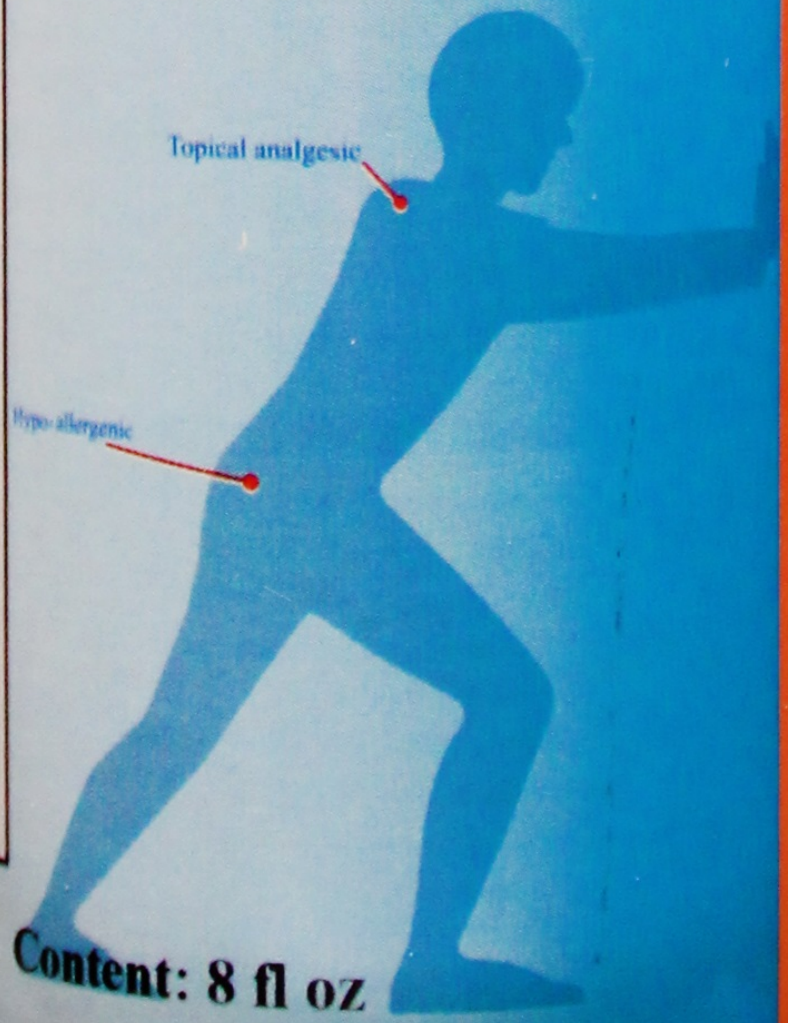
Indications and Usage

For the temporary relief of minor aches and pains, arthritis pain, backache,muscle vstrains and sprains. Make sure to clean the affected area then apply lotion and rub into the skin until it absorbs.


TheraDerm®
Pain RELIEVING
NDC#: 16903-

Lotion

Integrating Cryotherapy with Frankincense, Myrrh & Saffron



Content: 8 fl oz

170-03

THERA DERM

methyl salicylate lotion

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:16903-170
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
CAMPHOR LEAF OIL (UNII: 51D0RGY52V) (CAMPHOR LEAF OIL - UNII:51D0RGY52V)	CAMPHOR LEAF OIL	6 mg in 240 mg
7-AMINODESACETOXYCEPHALOSPORANIC ACID (UNII: ANM3MSM8TN) (7-AMINODESACETOXYCEPHALOSPORANIC ACID - UNII:ANM3MSM8TN)	7-AMINODESACETOXYCEPHALOSPORANIC ACID	450 mg in 240 mg
MENTHOL, UNSPECIFIED FORM (UNII: L7T10EIP3A) (MENTHOL, UNSPECIFIED FORM - UNII:L7T10EIP3A)	MENTHOL, UNSPECIFIED FORM	13 mg in 240 mg
METHYL SALICYLATE 2-ETHYLBUTYRATE (UNII: J8D9175Q0G) (METHYL SALICYLATE 2-ETHYLBUTYRATE - UNII:J8D9175Q0G)	METHYL SALICYLATE 2-ETHYLBUTYRATE	28 mg in 240 mg
PEPPERMINT OIL (UNII: AV092KU4JH) (PEPPERMINT - UNII:V95R5KMY2B)	PEPPERMINT OIL	13 mg in 240 mg

Inactive Ingredients	
Ingredient Name	**Strength**
PAEONIA LACTIFLORA FLOWER (UNII: R73687A534)	4 mg in 240 mg
SALVIA MILTIORRHIZA ROOT (UNII: 1693AM5SBN)	4 mg in 240 mg
ANGELICA SINENSIS ROOT OIL (UNII: T8CL3168L1)	4 mg in 240 mg
LIGUSTICUM SINENSE SUBSP. CHUANXIONG ROOT (UNII: RR83T99U97)	4 mg in 240 mg
12-HYDROXYSTEARIC ACID (UNII: 933ANU3H2S)	15 mg in 240 mg
MYRRH OIL (UNII: H74221J5J4)	4 mg in 240 mg
LAVENDER OIL (UNII: ZBP1YXW0H8)	3 mg in 240 mg
PERSICARIA FILIFORMIS FLOWERING TOP (UNII: M4VKX9Q8AJ)	4 mg in 240 mg
NOTOPTERYGIUM INCISUM ROOT (UNII: 5Z2WW4J6RI)	4 mg in 240 mg
ANGELICA PUBESCENS ROOT (UNII: 0MF1EI01KJ)	4 mg in 240 mg
ZINGIBER CASSUMUNAR ROOT OIL (UNII: O47HX41O6C)	4 mg in 240 mg
COCONUT OIL (UNII: Q9L0O73W7L)	4 mg in 240 mg
ALOE (UNII: V5VD430YW9)	7.5 mg in 240 mg
CARTHAMUS TINCTORIUS FLOWER OIL (UNII: SDQ136WIM5)	4 mg in 240 mg
FRANKINCENSE OIL (UNII: 67ZYA5T02K)	4 mg in 240 mg

Product Characteristics			
Color	white	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:16903-170-03	240 mg in 1 BOTTLE; Type 0: Not a Combination Product	10/31/2017	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		10/31/2017	

Labeler - Manna Omni International Incorporated (019109468)

Registrant - Manna Omni International Incorporated (019109468)

Establishment

Name	Address	ID/FEI	Business Operations
Manna Omni International Incorporated		019109468	manufacture(16903-170)

Revised: 2/2018 Manna Omni International Incorporated