

Theraderm- methyl salicylate 2-ethylbutyrate spray
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 Spray

Warning: For External Use Only.

Use only as directed. Avoid contact with eyes or mucous membranes. Do not apply to worn, 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 7 days, discontinue use and consult a physician.

Keep out of the reach of Children.

If swallowed, get medical attention or contact poison control immediately.

Directions: Spray a small amount onto affected area. Repeat 3-4 times daily.

Dosage:

Spray small amount onto affected area every 6 hours no more than 4 times a day.

Other Ingredients:

Aloe Extract, amelopsis radix extract, bletilla tuber extract, Carthamus extract, cimicifugae rhizome extract, echinopsis radix extract, glycerin, glycyrrhizae radix extract, kaolin, methyl salicylate, myrrh extract, frankincense extract, Poly Acrylic acid, polysorbate 80, polyvinyl alcohol, propyl glycol, propyl paraben, purified water, rhei rhizome extract, titanium oxide, triethanolamine, glucosamine, and MSM.

Active Ingredients:

Methyl Salicylate, Menthol Natural (From Peppermint oil), and Menthol Crystal Solution.

Purpose:

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

Use:

For the temporary relief of minor muscle pain, simple back aches, muscle strain or sprain.

Theraderm Pain Relieving Spray



THERADERM

methyl salicylate 2-ethylbutyrate spray

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:16903-169
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
PEPPERMINT OIL (UNII: AV092KU4JH) (PEPPERMINT - UNII:V95R5KMY2B)	PEPPERMINT	12 mg in 120 mg
METHYL SALICYLATE 2-ETHYLBUTYRATE (UNII: J8D9175Q0G) (METHYL SALICYLATE 2-ETHYLBUTYRATE - UNII:J8D9175Q0G)	METHYL SALICYLATE 2-ETHYLBUTYRATE	24 mg in 120 mg
MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	12 mg in 120 mg
CAMPHOR OIL (UNII: 75IZZ8Y727) (CAMPHOR OIL - UNII:75IZZ8Y727)	CAMPHOR OIL	5 mg in 120 mg

Inactive Ingredients

Ingredient Name	Strength
PRUNUS PERSICA SEED (UNII: V9C81470RR)	2 mg in 120 mg
(P-HYDROXYPHENYL)DIMETHYLSULFONIUM CHLORIDE (UNII: 33P1U651QS)	24 mg in 120 mg

ALOE VERA LEAF POLYSACCHARIDES (UNII: W21O437517)	1 mg in 120 mg
LIGUSTICUM SINENSE SUBSP. CHUANXIONG ROOT (UNII: RR83T99U97)	2 mg in 120 mg
FRANKINCENSE OIL (UNII: 67ZYA5T02K)	2 mg in 120 mg
MYRRH OIL (UNII: H74221J5J4)	2 mg in 120 mg
GLYCERIN (UNII: PDC6A3C0OX)	7 mg in 120 mg
COCONUT OIL (UNII: Q9L0O73W7L)	1 mg in 120 mg
LECITHIN, SOYBEAN (UNII: 1DI56QDM62)	3 mg in 120 mg
LAVENDER OIL (UNII: ZBP1YXW0H8)	1 mg in 120 mg
ANGELICA PUBESCENS ROOT (UNII: 0MF1E101KJ)	2 mg in 120 mg
ZINGIBER CASSUMUNAR ROOT (UNII: 3NG517NPD8)	2 mg in 120 mg

Product Characteristics

Color	yellow	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:16903-169-02	120 mg in 1 BOTTLE; Type 0: Not a Combination Product	03/17/2017	



Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		03/17/2017	

Labeler - Manna Omni International Incorporated (019109468)

Revised: 2/2018

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