

**THERAGESIC CREME- methyl salicylate cream**  
**Mainpointe Pharmaceuticals, 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.*

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**THERA-GESIC<sup>®</sup> Creme**

**Drug Facts**

**Active Ingredients Purpose**

Menthol 1%..... Analgesic  
Methyl Salicylate 15%..... Counterirritant

**Use**

temporary relief of minor aches and pains of muscles and joints associated with:

- arthritis
- simple backaches
- strains
- bruises
- sprains

**Warnings**

For external use only. Use only as directed. Avoid contact with eyes or mucous membranes.

Do not bandage, wrap, cover, use a heating pad after, or recline upon skin treated with THERA-GESIC<sup>®</sup>.

**Do not use**

- if skin is sensitive to oil of wintergreen (methyl salicylate)
- immediately shower or bath
- on wounds or damaged skin

**Ask a doctor before use**

- for children under 2 and to 12 years of age
- if prone or sensitive to allergic reaction from aspirin or salicylate

**When using this product**

- discontinue use if skin irritation develops, or redness is present
- do not swallow
- do not use a heating pad after application of THERA-GESIC<sup>®</sup>

Stop use and ask a doctor if condition worsens, or if symptoms persist for more than 7 days or clear up and occur again within a few days.

If pregnant or breast-feeding, ask a health professional before use.

Keep out of reach of children to avoid accidental poisoning. If swallowed, get medical help or contact a Poison Control Center right away.

**Other information**

Showering or washing the area after application of THERA-GESIC<sup>®</sup> will leave the area fragrance-free without diminishing the therapeutic effect. Avoid contact with clothing or other surfaces. Store at 20-25°C (68-77°F).

**Inactive ingredients**

Carbomer 934, dimethicone, glycerine, methylparaben, propylparaben, sodium laurel sulfate, trolamine, water

SHARE BEFORE USE: IT IS NORMAL FOR THIS PRODUCT TO GIVE THE IMPRESSION OF A LIQUID SOUND UON SHAKING. DO NOT ALLOW THERA-GESIC® TO COME IN CONTACT WITH ANY SURFACE, OTHER THAN SKIN. Do not use this product if tube is punctured. Lot number and expiration date on end of carton. MainPointe Pharmaceuticals, LLC Louisville, KY 40202 Rev 50563R1218

Directions Adults and children 12 or more years of age. Apply thin layers of crème into and around the sore or painful area, not more than 3 to 4 times daily. The number of thin layers controls the intensity of the action of THERA-GESIC®. One thin layer provides a mild effect, two thin layers provide a strong effect and three thin layers provide a very strong effect. SEE WARNINGS. Wash hands thoroughly after application.

**THERA-GESIC 3-oz**



| <b>THERAGESIC CREME</b>                |                |                           |               |
|--|----------------|---------------------------|---------------|
| methyl salicylate cream                |                |                           |               |
| <b>Product Information</b>             |                |                           |               |
| <b>Product Type</b>                    | HUMAN OTC DRUG | <b>Item Code (Source)</b> | NDC:71269-005 |
| <b>Route of Administration</b>         | TOPICAL        |                           |               |
| <b>Active Ingredient/Active Moiety</b> |                |                           |               |

| Ingredient Name   |  | Basis of Strength                                 | Strength             |                    |
|---|--|---|----------------------|--------------------|
| METHYL SALICYLATE (UNII: LAV5U5022Y) (SALICYLIC ACID - UNII:O414PZ4LPZ) |  | METHYL SALICYLATE                                 | 150 mg in 1 g        |                    |
| MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)                  |  | MENTHOL   | 10 mg in 1 g         |                    |
| <b>Inactive Ingredients</b>   |  |   |                      |                    |
| Ingredient Name   |  | Strength  |                      |                    |
| WATER (UNII: 059QF0KO0R)  |  |   |                      |                    |
| DIMETHICONE (UNII: 92RU3N3Y1O)  |  |   |                      |                    |
| GLYCERIN (UNII: PDC6A3C0OX)   |  |   |                      |                    |
| CARBOMER 934 (UNII: Z135WT9208)   |  |   |                      |                    |
| TROLAMINE (UNII: 9O3K93S3TK)  |  |   |                      |                    |
| METHYL PARABEN (UNII: A2I8C7HI9T)                                       |  |   |                      |                    |
| SODIUM LAURYL SULFATE (UNII: 368GB5141J)                                |  |   |                      |                    |
| PROPYL PARABEN (UNII: Z8IX2SC1OH)                                       |  |   |                      |                    |
| <b>Packaging</b>  |  |   |                      |                    |
| #   | Item Code                                | Package Description                               | Marketing Start Date | Marketing End Date |
| 1   | NDC:71269-005-03                         | 1 in 1 CARTON                                     | 12/01/2018           |                    |
| 1   |  | 85 g in 1 TUBE; Type 0: Not a Combination Product |                      |                    |
| <b>Marketing Information</b>  |  |   |                      |                    |
| Marketing Category  | Application Number or Monograph Citation | Marketing Start Date                              | Marketing End Date   |                    |
| OTC monograph not final   | part348                                  | 01/01/1981  |                      |                    |

**Labeler** - Mainpointe Pharmaceuticals, LLC (080544378)

**Registrant** - Mission Pharmacal Company (927726893)

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Mainpointe Pharmaceuticals, LLC