

THERAGESIC PLUS- methyl salicylate gel
Mission Pharmacal Company

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.

Theragesic Plus

Drug Facts

Active Ingredients

Methyl Salicylate

25%.....

Counterirritant

Menthol

4%.....

Analgesic

Purpose

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® PLUS.

Do not use

- immediately shower or bath
- if skin is sensitive to oil of wintergreen (methyl salicylate)
- 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® PLUS

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.

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® PLUS. 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.

Other information

Showering or washing the area after application of THERA-GESIC® PLUS 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

Aloe Vera, Carbomer Homopolymer Type C, Dimethicone, Glycerine, Methylparaben, Propylparaben, Sodium Lauryl Sulfate, Trolamine, Water.

To Report a serious adverse event or obtain product information, call (210) 696-8400

SHARE BEFORE USE: IT IS NORMAL FOR THIS PRODUCT TO GIVE THE IMPRESSION OF A LIQUID SOUND UON SHAKING. DO NOT ALLOW THERA-GESIC® PLUS TO COME IN CONTACT WITH ANY SURFACE, OTHER THAN SKIN.

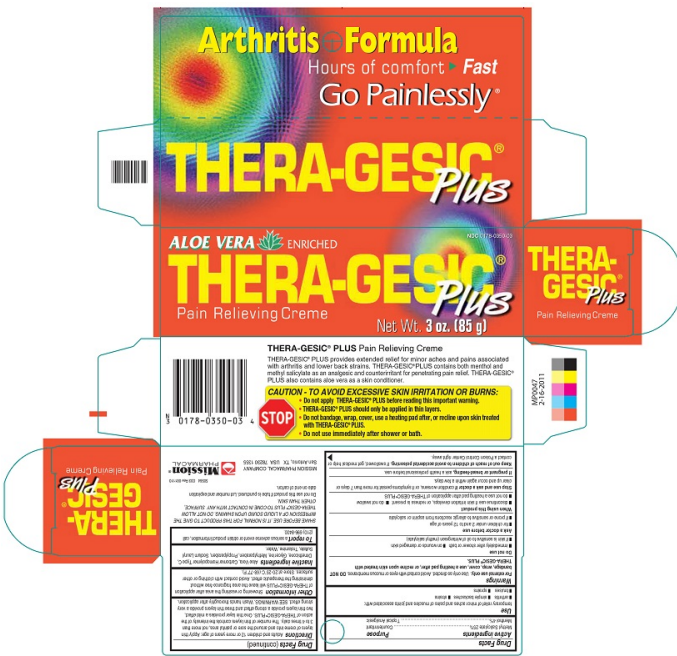
Do not use this product if tube is punctured. Lot number and expiration date on end of carton.

MISSION PHARMACAL COMPANY, San Antonio, TX 78230 1355

50564 C03 Rev 001110

THERA-GESIC® PLUS Carton

NDC: 0178-0350-03



SHAKE BEFORE USE. IT IS NORMAL FOR THIS PRODUCT TO GIVE THE IMPRESSION OF A LIQUID SOUND UPON SHAKING. DO NOT ALLOW THERA-GESIC® PLUS TO COME IN CONTACT WITH ANY SURFACE OTHER THAN SKIN. Lot number and expiration date on end of tube. 30186 C16 Rev 10/11/10

NDC 0178-0350-03

ALOE VERA ENRICHED

THERA-GESIC® PLUS

Pain Relieving Creme

Net Wt. 3oz. (85 g)

Do not use this product if tube is punctured. MISSION PHARMACAL COMPANY, San Antonio, TX USA 78230 1355

<p>Drug Facts</p> <p>Active ingredients Methyl Salicylate 25% Menthol 4%</p> <p>Purpose Counterirritant Topical Analgesic</p> <p>Use temporary relief of minor aches and pains of muscles and joints associated with: ■ arthritis ■ simple backaches ■ strains ■ bruises ■ sprains</p> <p>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® PLUS. Do not use ■ immediately after shower or bath ■ if skin is sensitive to oil of wintergreen (methyl salicylate) ■ on wounds or damaged skin Ask a doctor before use ■ for children under 2</p>	<p>Drug Facts (continued)</p> <p>and to 12 years of age ■ if prone or sensitive to allergic reactions from aspirin or salicylate</p> <p>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® PLUS</p> <p>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.</p> <p>If pregnant or breast-feeding, ask a health professional before use.</p> <p>Keep out of reach of children to avoid accidental poisoning. If swallowed, get medical help or contact a Poison Control Center right away.</p> <p>Directions Adults and children 12 or more years of age: Apply thin layers of creme into and around the sore or painful area, not more than 3 to 4 times daily. The number of thin layers controls the</p>	<p>Drug Facts (continued)</p> <p>intensity of the action of THERA-GESIC® PLUS. 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.</p> <p>Other information Showering or washing the area after application of THERA-GESIC® PLUS 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).</p> <p>Inactive ingredients Aloe Vera, Copolymer Homopolymer Type C, Dimethicone, Glycerine, Methylparaben, Propylparaben, Sodium Lauryl Sulfate, Tetralin, Water.</p> <p>To report a serious adverse event or obtain product information, call (210) 695-8400.</p>
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THERAGESIC PLUS				
methyl salicylate gel				
Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:0178-0350	
Route of Administration	TOPICAL			
Active Ingredient/Active Moiety				
Ingredient Name	Basis of Strength	Strength		
METHYL SALICYLATE (UNII: LAV5U022Y) (SALICYLIC ACID - UNIEO414PZ4LPZ)	METHYL SALICYLATE	250 mg in 1 g		
MENTHOL (UNII: 17T10EIP3A) (MENTHOL - UNIE17T10EIP3A)	MENTHOL	40 mg in 1 g		
Inactive Ingredients				
Ingredient Name	Strength			
WATER (UNII: 059QF0K00R)				
DIMETHICONE (UNII: 9ZR3N3Y1O)				
GLYCERIN (UNII: PDC6A3C0OX)				
CARBOMER 934 (UNII: Z135WT9208)				
TROLAMINE (UNII: 9O3K93S3TK)				
METHYLPARABEN (UNII: A2B2C7H9T)				
SODIUM LAURYL SULFATE (UNII: 368GB514J)				
PROPYLPARABEN (UNII: Z8IX2SC1OH)				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0178-0350-03	1 in 1 CARTON	01/01/1981	
1		85 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	01/01/1981	

Labeler - Mission Pharmacal Company (008117095)**Registrant** - Mission Pharmacal Company (927726893)**Establishment**

Name	Address	ID/FEI	Business Operations
Mission Pharmacal Company		927726893	manufacture(0178-0350)

Revised: 8/2019

Mission Pharmacal Company