

THERAGESIC CREME- methyl salicylate gel
A-5 Medication Solutions

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.

THERA-GESIC® 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®.

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®

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®. 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® 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

Questions (210) 696-8400 (M-Th 8:00-5:30 CST)

SHARE BEFORE USE: IT IS NORMAL FOR THIS PRODUCT TO GIVE THE IMPRESSION OF A LIQUID SOUND UPON 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.

MISSION PHARMACAL COMPANY, San Antonio, TX 78230 1355

50588 03 Rev 001090

THERA-GESIC 5-oz

Product: 50090-0430

NDC: 50090-0430-0 85 g in a TUBE / 1 in a CARTON

METHYL SALICYLATE



THERAGESIC CREME

methyl salicylate gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:50090-0430(NDC:0178-0320)
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
METHYL SALICYLATE (UNII: LAV5U502ZY) (SALICYLIC ACID - UNII:0414PZ4LPZ)	METHYL SALICYLATE	150 mg in 1 g
MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	10 mg in 1 g

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0K00R)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
GLYCERIN (UNII: PDC6A3C00X)	

CARBOMER HOMOPOLYMER TYPE B (ALLYL SUCROSE CROSSLINKED) (UNII: Z135W9208)
 TROLAMINE (UNII: 9Q3K9353TX)
 METHYLPARABEN (UNII: A28C7H9T)
 SODIUM LAURYL SULFATE (UNII: 368GB5141J)
 PROPYLPARABEN (UNII: Z8IX25C1OH)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:50090-0430-0	1 in 1 CARTON	11/28/2014	
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 - A-S Medication Solutions (830016429)

Establishment

Name	Address	ID/FEI	Business Operations
A-S Medication Solutions		830016429	RELABEL(50090-0430)

Revised: 4/2021

A-S Medication Solutions