

THERA-GEL- coal tar shampoo
Major Pharmaceuticals

Major® Thera-Gel™ Therapeutic
Anti-Dandruff

Drug Facts

Active ingredient

Solubilized Coal Tar Extract 2.50% (Coal Tar, 0.50%)

Purpose

Anti-dandruff, anti-seborrheic dermatitis, anti-psoriasis

Use

controls the symptom of:

- dandruff
- seborrheic dermatitis
- psoriasis

Warnings

For external use only.

Ask a doctor before use if you have a condition that covers a large area of the body.

When using this product

- avoid contact with the eyes. If contact occurs, rinse eyes thoroughly with water
- use caution in exposing skin to sunlight after applying this product. It may increase your tendency to sunburn for up to 24 hours after application.
- do not use for prolonged periods without consulting a doctor.
- do not use this product with other forms of psoriasis therapy such as ultraviolet radiation or prescription drugs unless directed to do so by a doctor.

Stop use and ask a doctor if condition worsens or does not improve after regular use of this product as directed.

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center (1-800-222-1222) right away.

Directions

- for best results use at least twice a week or as directed by a doctor
- wet hair thoroughly
- massage shampoo into the scalp
- lather, leave on hair and scalp for several minutes.
- rinse and repeat

Other information

- store away from direct sunlight
- in rare instances, discoloration of gray, blonde, bleached or tinted hair may occur

Inactive ingredients

water, sodium laureth sulfate, cocamide MEA, cocamidopropyl betaine, laureth-4, fragrance, polysorbate 20, citric acid, sodium chloride, disodium EDTA, phenoxyethanol, methylchloroisothiazolinone, methylisothiazolinone, red 40, blue 1, yellow 5, yellow 6.

Questions or comments?

1-866-567-8600

Distributed By: MAJOR® PHARMACEUTICALS

17177 N Laurel Park Dr., Suite 233
Livonia, MI 48152, USA

PRINCIPAL DISPLAY PANEL - 251 mL Bottle Label

NDC 0904-5259-44

MAJOR®

Thera-Gel™
THERAPEUTIC
SHAMPOO

ORIGINAL FORMULA

Coal Tar 0.5%

Long Lasting Relief of
Itching and Flaking

Controls the Symptoms of:

- Seborrheic Dermatitis
- Psoriasis
- Dandruff

05-1439A

*Compare to the active ingredient of

Neutrogena[®] T/Gel[®] Therapeutic Shampoo

8.5 FL OZ (251 mL)

NDC 0904-5259-44



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Inactive ingredients

water, sodium laureth sulfate, cocamide MEA, cocamidopropyl betaine, laureth-4, fragrance, polysorbate 20, citric acid, sodium chloride, tetrasodium EDTA, DMDM hydantoin, caramel, red 40

Questions or comments?

adverse drug event call: 800-616-2471

073-217B

Distributed By: MAJOR® PHARMACEUTICALS
17177 N Laurel Park Dr., Suite 233
Livonia, MI 48152, USA

*This product is not manufactured or distributed by Neutrogena, Corporation, owner of the registered trademark Neutrogena® T/Gel®.

Made in Canada Reorder No. 241969 M-104.
Rev. 01/17



05-1440D

Thera-Gel

coal tar shampoo

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:0904-5259
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Coal Tar (UNII: R533ESO2EC) (Coal Tar - UNII:R533ESO2EC)	Coal Tar	5 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
Water (UNII: 059QF0KO0R)	
Sodium Laureth-3 Sulfate (UNII: BPV390UAP0)	
Cocamidopropyl Betaine (UNII: 5OCF3O11KX)	
Laureth-4 (UNII: 6HQ855798J)	
Sodium Chloride (UNII: 451W47IQ8X)	
Edetate Sodium (UNII: MP1J8420LU)	

Product Characteristics

Color	brown	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0904-5259-44	251 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	05/18/2010	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M032	05/18/2010	

Labeler - Major Pharmaceuticals (191427277)

Registrant - Garcoa, Inc. (036464697)

Establishment

Name	Address	ID/FEI	Business Operations
Sigan America, LLC		964976968	manufacture(0904-5259)

Revised: 5/2024

Major Pharmaceuticals