

MAJOR THERA-GEL THERAPEUTIC ANTI-DANDRUFF- 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



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05-1440D

MAJOR THERA-GEL THERAPEUTIC ANTI-DANDRUFF

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