

## **MAJOR THERA-GEL THERAPEUTIC ANTI-DANDRUFF- coal tar shampoo**

### **Major Pharmaceuticals**

*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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### **Major® Thera-Gel™ Therapeutic Anti-Dandruff**

#### **Drug Facts**

#### **Active ingredient**

Solubilized Coal Tar Extract 2.5% (Coal Tar, 0.5%)

#### **Purpose**

Anti-dandruff

#### **Use**

controls the symptom of:

- ◆ dandruff
- ◆ seborrheic dermatitis
- ◆ psoriasis

#### **Warnings**

##### **For external use only**

**Ask a doctor before use if you have** a condition which covers a large part of the body

##### **When using this product**

- ◆ do not get into 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 with other forms of psoriasis therapy such as ultra violet 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 right away.

## Directions

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

## 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, tetrasodium EDTA, DMDM hydantoin, caramel, red 40

## Questions or comments?

Adverse drug event call: **800-616-2471**

### **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)

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073-217B

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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

# MAJOR THERA-GEL THERAPEUTIC ANTI-DANDRUFF

coal tar shampoo

## Product Information

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

## Active Ingredient/Active Moiety

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

## Inactive Ingredients

<b>Ingredient Name</b>	<b>Strength</b>
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

<b>Color</b>	BROWN	<b>Score</b>	
<b>Shape</b>		<b>Size</b>	
<b>Flavor</b>		<b>Imprint Code</b>	
<b>Contains</b>			

## 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

<b>Marketing Category</b>	<b>Application Number or Monograph Citation</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
OTC MONOGRAPH FINAL	part358H	09/01/2007	

**Labeler** - Major Pharmaceuticals (191427277)

**Registrant** - Garcoa, Inc. (036464697)

**Establishment**

<b>Name</b>	<b>Address</b>	<b>ID/FEI</b>	<b>Business Operations</b>
Sigan Industries INC.		255106239	MANUFACTURE(0904-5259)

Revised: 1/2022

Major Pharmaceuticals