

TERA-GEL- coal tar shampoo
Geritrex LLC

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.

Tera-Gel Shampoo

Active Ingredient

Active Ingredient Purpose

0.5% Coal Tar Anti-Dandruff, Anti-Seborrheic
Dermatitis, Anti-Psoriasis

Uses

To control the symptoms of dandruff,
seborrheic dermatitis, and psoriasis

Directions

For best results, use at least twice a week or as directed by a physician.

- Wet hair and scalp thoroughly.
- Massage shampoo into scalp.
- Leave lather on hair and scalp for several minutes.
- Rinse and repeat

For best results, use at least twice a week or as directed by a physician.

Warnings

FOR EXTERNAL USE ONLY

Consult a physician before use if you have a condition that covers a large area of the body. Consult a physician or pharmacist before using if you intend to use this product with other forms of psoriasis therapy such as ultraviolet radiation or prescription drugs.

When using this product:

- Avoid contact with eyes. If contact occurs, rinse eyes thoroughly with water.
 - If improvement does not occur, or condition worsens after regular use, as directed, consult a physician.
 - Use caution when exposing skin to sunlight after using this product. It may increase the tendency to sunburn for up to 24 hours after using this product.
 - Do not use for prolonged periods without consulting a doctor.
- If condition worsens or does not improve after regular use of this product as directed, stop use and consult a physician.

15°-30°C (59°-86°F).

Keep out of reach of children. If swallowed get prompt medical attention or contact a poison control center immediately.

Inactive Ingredients:

Black Shade R, Citric Acid, Cocamide MEA, Cocamidopropyl Betaine, Deionized Water, DMDM Hydantoin, FD&C Red #33, Fragrance, Methylparaben, Propylparaben, Sodium Chloride, Sodium Laureth Sulfate, Tetrasodium EDTA.



54162-250-80

Geritrex®

Tera-Gel™

TAR SHAMPOO

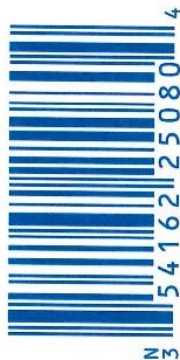
Soothes symptoms of

- Psoriasis
- Dandruff
- Seborrheic Dermatitis

Contains:

Solubilized Coal Tar

8 FL. OZ. (237 mL)



Drug Facts

Active Ingredient	Purpose
Coal Tar 0.5%	Anti-Dandruff, Anti-Seborrheic Dermatitis, Anti-Psoriasis

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STORE AT ROOM TEMPERATURE 15°-30°C (59°-86°F).

For Questions, Comments or Information
Call 1-800-736-3437

WARNING: This product contains agents known to the State of California to cause cancer & birth defects.

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Mount Vernon, NY 10550
1-800-736-3437
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TERA-GEL

coal tar shampoo

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:54162-250
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
COAL TAR (UNII: R533ESO2EC) (COAL TAR - UNII:R533ESO2EC)	COAL TAR	1.365 g in 237 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
COCO DIETHANOLAMIDE (UNII: 92005F972D)	
POLYSORBATE 20 (UNII: 7T1F30V5YH)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
COCAMIDOPROPYL BETAINE (UNII: 5OCF3O11KX)	
DMDM HYDANTOIN (UNII: BYR0546TOW)	
METHYL PARABEN (UNII: A2I8C7HI9T)	
PROPYL PARABEN (UNII: Z8IX2SC1OH)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
SODIUM LAURETH SULFATE (UNII: BPV390UAP0)	
EDETATE SODIUM (UNII: MPLJ8420LU)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:54162-250-80	237 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part358H	07/31/2015	

Labeler - Geritrex LLC (112796248)

Revised: 1/2016

Geritrex LLC