

PC-TAR- 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.

PC-TAR

Active Ingredient:
Coal Tar 1%

Purpose:

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

Intended Uses:

To provide temporary relief to itchy, dry, and/or flaky scalp conditions

Directions:

Shake well before using

Wet hair and scalp thoroughly

Massage shampoo into hair and scalp and work into a rich lather

Leave shampoo on hair for several minutes

Rinse and repeat

Rinse thoroughly with water

Warnings:

If condition covers a large part of the body, consult a physician before using this product

When using this shampoo protect the treated area from direct sunlight. It may increase your tendency to sunburn for up to 24 hours after using this product.

In rare instances hair discoloration may occur to gray, blonde, bleached, or tinted hair.

Do not use for prolonged periods without consulting a physician.

If improvement does not occur, or condition worsens after regular use or as directed, consult a physician

FOR EXTERNAL USE ONLY

☐KEEP OUT OF REACH OF CHILDREN

In case of accidental ingestion, seek prompt medical attention or contact a Poison Control Center immediately.

Avoid contact with the eyes. If contact occurs, rinse thoroughly with water.

☐Inactive Ingredients:

Purified water, Cocamide DEA, Polysorbate 20 & 80, Cocamphocarboxy Glyceride, EDTA, Fragrance, Magnesium Aluminum Silicate, PEG-75 Lanolin, Hexeylene Glycol, Sodium Polnaphthalene Sulfonate, 0.5% Parachlorometaxlylenol (antimicrobial preservative)

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



54162-200-06

PC-TAR™
Golden Lathering
SHAMPOO

For Itchy and Flaking Scalp
Recommended for the
Temporary Relief of Itching
Associated with Dandruff
Contains Coal Tar and PCMX

6 FL. OZ.

FOR EXTERNAL USE ONLY

Drug Facts	
Active Ingredient 1% Coal Tar	Purpose Anti-Dandruff, Anti-Seborrheic Dermatitis, Anti-Psoriasis
Intended Uses: To provide temporary relief to itchy, dry and/or flaky scalp conditions.	
Directions: • Shake well before using. • Wet hair and scalp thoroughly. • Massage shampoo into hair and scalp and work into a rich lather. • Leave shampoo on hair for several minutes. • Rinse and repeat. • Rinse thoroughly with clear water.	
Warnings	
<ul style="list-style-type: none"> • If condition covers a large part of the body, consult a physician before using this product. • When using this shampoo protect the treated area from direct sunlight. It may increase your tendency to sunburn for up to 24 hours after using this product. • In rare instances hair discoloration may occur to gray, blonde, bleached, or tinted hair. • Do not use for prolonged periods without consulting a physician. • If improvement does not occur, or condition worsens after regular use, as directed, consult a physician. • For External Use Only • Keep Out of Reach of Children • In cases of accidental ingestion, seek prompt medical attention or contact a Poison Control Center immediately. • Avoid contact with eyes. If contact occurs, rinse eyes thoroughly with water. 	
Inactive Ingredients: Purified Water, Cocamide DEA, Polysorbates 20 & 80, Cocamphocarboxy Glycidate, EDTA, Fragrance, Magnesium Aluminum Silicate, PEG-75 Lanolin, Hexeylene Glycol, Sodium Polnaphthalene Sulfonate, 0.5% Parachlorometaxlylenol (Antimicrobial Antiseptic, Preservative)	
For Questions, Comments or Information Call 1-800-736-3437	



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PC-TAR

coal tar shampoo

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:54162-200
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
COAL TAR (UNII: R533ESO2EC) (COAL TAR - UNII:R533ESO2EC)	COAL TAR	1.77441 g in 177.441 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
COCAMIDE (UNII: 3YXD33R71G)	
POLYSORBATE 20 (UNII: 7T1F30V5YH)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
EDETIC ACID (UNII: 9G34HU7RV0)	
MAGNESIUM ALUMINUM SILICATE (UNII: 6M3P64V0NC)	
PEG-75 LANOLIN (UNII: 09179OX7TB)	
HEXYLENE GLYCOL (UNII: KEH0A3F75J)	
NAPHTHALENESULFONIC ACID (MIXED ISOMERS) (UNII: VZW67VII75)	
CHLOROXYLENOL (UNII: 0F32U78V2Q)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:54162-200-06	177.441 mL in 1 BOTTLE; Type 0: Not a Combination Product	07/31/2015	

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)

Establishment

Name	Address	ID/FEI	Business Operations
Geritrex LLC		112796248	manufacture(54162-200)

Revised: 7/2016

Geritrex LLC