

ARCA REGENERATION HEAD SPA- pinus radiata bark extract, menthol, salicylic acid shampoo

Hair Arca, Inc

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.

83104-301 ARCA Regeneration Head Spa

Active ingredients

Pinus Radiata Bark Extract 0.05%

Menthol 0.5%

Salicylic Acid 0.5%

Purpose

Pinus Radiata Bark Extract 0.05% - Skin Protectant

Menthol 0.5% - Dandruff Control

Salicylic Acid 0.5% - Dandruff Control

Uses

Helps to keep scalp healthy by controlling follicle and protecting skin.

If used together with other Arca hair products, helps hair enrichment and decreases the risks of hair loss and various scalp troubles.

Warnings

For external use only.

Warnings

When using this product keep out of eyes.

Rinse with water to remove.

Warnings

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

Warnings

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

Warnings

Do not use on damaged or broken skin.

Directions

ARCA REGENERATION HEAD SPA recommends the following instructions for scalp improvement and skin troubles.

(Head Spa is recommended to use 2~3 times a week)

- 1 SHAMPOO your hair with ARCA SHAMPOO before using the head spa
- 2 Use 1-3 pumps to massage your scalp and hair. Then wait 2 to 3 minutes.
- 3 Rinse thoroughly with warm water.

Inactive Ingredients

Aqua, Cetyl Alcohol, Hydroxyethylcellulose, Quaternium-87, Stearamidopropyl Dimethylamine, Cetrimonium Chloride, Steartrimonium Chloride, PPG-3 Caprylyl Ether, Hydroxyethylcellulose, Ricinus Communis(Castor) Seed Oil, Camellia Japonica Seed Oil, Helianthus Annuus (Sunflower) Seed Oil, Behentrimonium Methosulfate, Stearyl Alcohol, Propylene Glycol, Panthenol, Butylene Glycol, Lavandula Angustifolia (Lavender) Flower Extract, Monarda Didyma Leaf Extract, Mentha Piperita (Peppermint) Leaf Extract, Freesia

Refracta Extract, Chamomilla Recutita(Matricaria) Flower Extract, Rosmarinus Officinalis (Rosemary) Leaf Extract, Avena Sativa

(Oat) Kernel Extract, Gelatin, Hydrolyzed Keratin, Hydrolyzed Collagen, Hydrolyzed Corn Protein, Hydrolyzed Soy Protein, Hydrolyzed Wheat Protein, Sodium Benzoate, Citric acid, 1,2-Hexanediol, Caprylyl Glycol, Ethylhexylglycerin, Allantoin, Disodium EDTA, fragrance, Limonene

Display panel

83104-401

ARCA

REGENERATION HEAD SPA

100% NEW ZEALAND GENOL FROM PINUS RADIATA STUMP

ARCAGENOL REGENERATION SCIENCE

TO KEEP ALIVE AND REGENERATE

HAIR LOSS CONTROL via SCALP REGENERATION · FOLLICLE CONTROL · HAIR ENRICHMENT



1/3
ARCAGENOL
POINT

17oz

DRUG FACTS

ACTIVE INGREDIENTS	PURPOSE
Pinus Radiata	
Bark Extract 0.05%	Skin Protectant
Menthol 0.5%	Dandruff Control
Salicylic Acid 0.5%	Dandruff Control

USES: Helps to keep scalp healthy by controlling follicle and protecting skin. If used together with other Arca hair products, helps hair enrichment and decreases the risks of hair loss and various scalp troubles.

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ARCA REGENERATION HEAD SPA

Manufactured by Korea Beauty Medipharm co., LTD. 402, C-dong, 47beon-gil4, Gajeong-ro, Seo-gu, Incheon, Korea
 Distributed by HAIR ARCA
 3660 Whilshire Blvd Suite 101, Los Angeles, CA 90010
 Quantity: 17oz
 Contact: 213.380.0247

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MADE IN KOREA
www.arcagenolus.com

ARCA REGENERATION HEAD SPA

pinus radiata bark extract, menthol, salicylic acid shampoo

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:83104-301
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
SALICYLIC ACID (UNII: O414PZ4LPZ) (SALICYLIC ACID - UNII:O414PZ4LPZ)	SALICYLIC ACID	0.5 g in 100 mL

Inactive Ingredients

Ingredient Name	Strength
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
STEARYL ALCOHOL (UNII: 2KR89I4H1Y)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
MONARDA DIDYMA LEAF (UNII: JY15982UBB)	
MENTHA PIPERITA LEAF (UNII: A389O33LX6)	
CHAMOMILE (UNII: FGL3685T2X)	
ROSEMARY (UNII: IJ67X351P9)	
FREESIA ALBA WHOLE (UNII: SS55L6C3QQ)	
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	
OAT (UNII: Z 6J799EAJK)	
PPG-10 CAPRYLYL ETHER (UNII: B1ML6JO7Z2)	

CASTOR OIL (UNII: D5340Y2I9G)
SUNFLOWER OIL (UNII: 3W1JG795YI)
BEHENTRIMONIUM METHOSULFATE (UNII: 5SHP745C61)
PANTHENOL (UNII: WW9CM0067Z)
HYDROXYETHYL CELLULOSE, UNSPECIFIED (UNII: T4V6TWG28D)
GELATIN (UNII: 2G86QN327L)
HYDROLYZED WHEAT PROTEIN (ENZYMATIC, 3000 MW) (UNII: J2S07SB0YL)
EDETATE DISODIUM ANHYDROUS (UNII: 8NLQ36F6MM)
CAMELLIA JAPONICA SEED OIL (UNII: U37N0S910T)
HYDROLYZED SOY PROTEIN (ENZYMATIC; 2000 MW) (UNII: 1394NXB9L6)
CETRIMONIUM CHLORIDE (UNII: UC9PE95IBP)
WATER (UNII: 059QF0K00R)
TRIMETHYL OCTADECYL AMMONIUM CHLORIDE (UNII: CZ70647U92)
LAVANDULA ANGUSTIFOLIA SUBSP. ANGUSTIFOLIA FLOWER (UNII: 19AH1RAF4M)
CETYL ALCOHOL (UNII: 936JST6JCN)
STEARAMIDOPROPYL DIMETHYLAMINE (UNII: K7VEI00UFR)
SODIUM BENZOATE (UNII: OJ245FE5EU)
1,2-HEXANEDIOL (UNII: TR046Y3K1G)
ALLANTOIN (UNII: 344S277G0Z)
BUTYLENE GLYCOL (UNII: 3XUS85K0RA)
CAPRYLYL GLYCOL (UNII: 00YIU5438U)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:83104-301-01	503 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	10/03/2022	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	M032	10/03/2022	

Labeler - Hair Arca, Inc (106984414)

Registrant - Hair Arca, Inc (106984414)

Establishment

Name	Address	ID/FEI	Business Operations
Gopher Co., Ltd.		695650633	manufacture(83104-301)