

BIOTOP PROFESSIONAL 02 ECO DANDRUFF- salicylic acid shampoo
G.V. COSMETICS LTD

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.

BIOTOP® PROFESSIONAL 02 Eco Dandruff

Drug Facts

Active ingredient

Salicylic acid 2% w/v

Purpose

Antidandruff

Use

helps eliminate scalp flaking associated with dandruff

Warnings

For external use only

Do not use

- on or by children • in case of damaged scalp
- if sensitive to any of its ingredients

When using this product • do not get into eyes. In case of contact, rinse eyes thoroughly with water

Stop use and ask a doctor if

- condition worsens or does not improve after regular use of this product as directed
- any irritation appears

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

Directions

- gently massage a generous amount of shampoo into the scalp until a lather forms
- leave in for 5 minutes and rinse
- for best results use at least twice a week or as directed by a doctor

Other information

- store at room temperature

Inactive ingredients

Water (Aqua), Sodium Coceth Sulfate, Chamomile (*Chamomilla recutita*) Flower Extract, Panthenol, Phenoxyethanol, PEG -150 Distearate, Ammonium Chloride, Piroctone Olamine, Polyquaternium-10, Glycol Distearate, Acrylates/C10-30 Alkyl Acrylate Crosspolymer, Fragrance (Parfum), Chlorphenesin, Laureth-4, Benzyl Benzoate, Caprylyl Glycol, Benzyl Salicylate, Cocamidopropyl Betaine, Citric Acid, Formic Acid, Sodium Acetate, Macadamia (*Macadamia ternifolia*) Seed Oil, Sea Buckthorn (*Hippophae rhamnoides*) Fruit Oil, Aloe (*Aloe barbadensis*) Juice, Sunflower (*Helianthus annuus*) Seed Oil, SD Alcohol 40, Glycerin, Hydrolyzed Keratin, Licorice (*Glycyrrhiza glabra*) Root Extract, Sage (*Salvia officinalis*) Extract, Sodium Benzoate, Benzyl Alcohol, Dipotassium EDTA, Potassium Sorbate

Questions?

+1-906-424-4591

You may also report serious side effects to this phone number.

Mon - Fri 9:00 AM - 5:00 PM

Soothes Dry Scalp

Parabens, SLS, SLES,
Sodium Chloride **free**

Manufactured by G.V. Cosmetics Ltd.

34 Ben-Zion Galis St., Segula, Petah Tikva, Israel, 4927934

Made in Israel

Packaging

Drug Facts (continued)

Inactive ingredients Water (Aqua), Sodium Coceth Sulfate Chamomile (*Chamomilla recutita*) Flower Extract, Panthenol, Phenoxyethanol, PEG -150 Distearate, Ammonium Chloride, Piroctone Olamine, Polyquaternium-10, Glycol Distearate, Acrylates/C10-30 Alkyl Acrylate Crosspolymer, Fragrance (Parfum), Chlorphenesin, Laureth-4, Benzyl Benzoate, Caprylyl Glycol, Benzyl Salicylate, Cocamidopropyl Betaine, Citric Acid, Formic Acid, Sodium Acetate, Macadamia (*Macadamia ternifolia*) Seed Oil, Sea Buckthorn (*Hippophae rhamnoides*) Fruit Oil, Aloe (*Aloe barbadensis*) Juice, Sunflower (*Helianthus annuus*) Seed Oil, SD Alcohol 40, Glycerin, Hydrolyzed Keratin, Licorice (*Glycyrrhiza glabra*) Root Extract, Sage (*Salvia officinalis*) Extract, Sodium Benzoate, Benzyl Alcohol, Dipotassium EDTA, Potassium Sorbate

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34 Ben-Zion Galis St., Segula, Petah Tikva, Israel, 4927934

Made in Israel
Lot no.:
Expiry:



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02
Eco Dandruff

**SALICYLIC ACID
ANTIDANDRUFF
SHAMPOO**

BIOTOP
PROFESSIONAL

Soothes Dry Scalp
Parabens, SLS, SLES,
Sodium Chloride **free**

250 mL (8.45 fl oz)

Drug Facts

Active ingredient	Purpose
Salicylic acid 2% w/v.....	Antidandruff

Use helps eliminate scalp flaking associated with dandruff

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Other information
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BIOTOP PROFESSIONAL 02 ECO DANDRUFF

salicylic acid shampoo

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC: 79096-032
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
SALICYLIC ACID (UNII: O414PZ4LPZ) (SALICYLIC ACID - UNII:O414PZ4LPZ)	SALICYLIC ACID	2 g in 100 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
SODIUM COCO-SULFATE (UNII: 3599J29ANH)	
CHAMOMILE (UNII: FGL3685T2X)	
PANTHENOL (UNII: WW9CM0O67Z)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
PEG-150 DISTEARATE (UNII: 6F36Q0I0AC)	
AMMONIUM CHLORIDE (UNII: 01Q9PC255D)	
PIROCTONE OLAMINE (UNII: A4V5C6R9FB)	
POLYQUATERNIUM-10 (10000 MPA.S AT 2%) (UNII: PI1STR9QYH)	
GLYCOL DISTEARATE (UNII: 13W7MDN21W)	
CARBOMER INTERPOLYMER TYPE B (ALLYL PENTAERYTHRITOL CROSSLINKED) (UNII: 132584PQMO)	
CHLORPHENESIN (UNII: I670DAL4SZ)	
LAURETH-4 (UNII: 6HQ855798J)	
BENZYL BENZOATE (UNII: N863NB338G)	

CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
BENZYL SALICYLATE (UNII: WAO5MNK9TU)	
COCAMIDOPROPYL BETAINE (UNII: 5OCF3O11KX)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
FORMIC ACID (UNII: 0YIW783RG1)	
SODIUM ACETATE (UNII: 4550K0SC9B)	
MACADAMIA OIL (UNII: 515610SU8C)	
HIPPOPHAE RHAMNOIDES FRUIT OIL (UNII: TA4JCF9S1J)	
ALOE (UNII: V5VD430YW9)	
SUNFLOWER OIL (UNII: 3W1JG795YI)	
ALCOHOL (UNII: 3K9958V90M)	
GLYCERIN (UNII: PDC6A3C0OX)	
HAIR KERATIN AMINO ACIDS (UNII: G46579QK1M)	
LICORICE (UNII: 61ZBX54883)	
SAGE (UNII: 065C5D077J)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
BENZYL ALCOHOL (UNII: LKG8494WBH)	
EDETATE DIPOTASSIUM ANHYDROUS (UNII: 3W5S57M958)	
POTASSIUM SORBATE (UNII: 1VPU26JZZ4)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:79096-032-25	250 mL in 1 BOTTLE; Type 0: Not a Combination Product	01/05/2023	
2	NDC:79096-032-50	500 mL in 1 BOTTLE; Type 0: Not a Combination Product	01/05/2023	
3	NDC:79096-032-10	1000 mL in 1 BOTTLE; Type 0: Not a Combination Product	01/05/2023	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part358H	01/05/2023	

Labeler - G.V. COSMETICS LTD (649551330)

Establishment

Name	Address	ID/FEI	Business Operations
G.V. COSMETICS LTD		649551330	manufacture(79096-032)