

**BIOTOP PROFESSIONAL 02 ECO DANDRUFF- salicylic acid solution**  
**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.*

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**BIOTOP® PROFESSIONAL 02 Eco Dandruff**

***Drug Facts***

***Active ingredient***

Salicylic acid 1.8% w/v

***Purpose***

Antidandruff

***Use***

reduces the symptoms of 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***

- after using Eco Dandruff shampoo, towel dry your hair, dispense 1 tube into hand, apply the solution directly to your scalp and massage well with your fingertips until dispersed fully and evenly
- apply to affected areas one to four times daily or as directed by a doctor

- do not wash
- recommended use:  
Women: 1 or 2 tubes per week for 2-3 months  
Men: 2 or 3 tubes per week for 3 months  
Preventive Follow-Up Treatment: 1 tube per week for 2 months

### ***Other information***

- store at room temperature

### ***Inactive ingredients***

Caprylyl Glycol, Chlorphenesin, FD&C Blue No. 1 (CI 42090), FD&C Yellow No. 5 (CI 19140), PEG-40 Hydrogenated Castor Oil, Phenoxyethanol, Piroctone Olamine, Polysorbate 20, PPG-26-Buteth-26, Propylene Glycol, SD Alcohol 40, Sodium Hydroxide, Water (Aqua)

### ***Questions?***

**+1-906-424-4591**

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

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

### **ANTIDANDRUFF**

Soothing Scalp Treatment  
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**

Responsible person in Europe  
LL&P Enterprises Ltd.  
P.O. Box 51445, Limassol 3505, Cyprus  
Email: [christiana@llpenterprises.com](mailto:christiana@llpenterprises.com)

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[www.biotopworld.com](http://www.biotopworld.com) | [Info@biotopworld.com](mailto:Info@biotopworld.com)

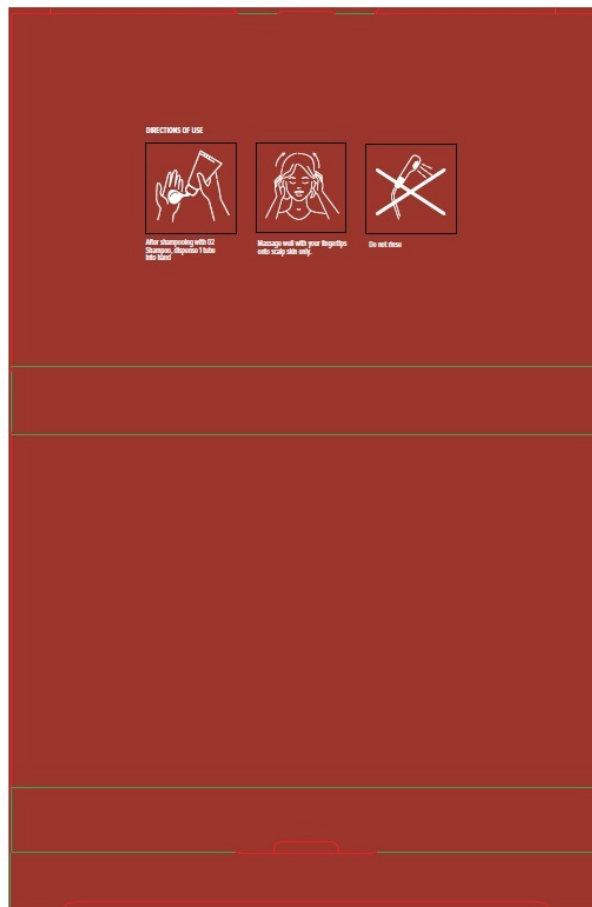
### **Packaging**

#### INNER TUBE LABEL





## OUTER BOX LABEL



## DRUG FACTS TABLE

Drug Facts	
<b>Active ingredient</b>	<b>Purpose</b>
Salicylic acid 1.8% w/v	Antidandruff
<b>Use</b>	
reduces the symptoms of dandruff	
<b>Warnings</b>	
<b>For external use only</b>	
<b>Do not use</b>	
<ul style="list-style-type: none"> <li>on or by children</li> <li>in case of damaged scalp</li> <li>if sensitive to any of its ingredients</li> </ul>	
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**Questions? +1-908-424-4501**  
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Mon - Fri 9:00 AM - 5:00 PM

BIOTOP PROFESSIONAL 02 ECO DANDRUFF

salicylic acid solution

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:79096-033
Route of Administration	TOPICAL		
Active Ingredient/Active Moiety			
Ingredient Name		Basis of Strength	Strength
SALICYLIC ACID (UNII: O414PZ4LPZ) (SALICYLIC ACID - UNII:O414PZ4LPZ)		SALICYLIC ACID	1.8 g in 100 mL
Inactive Ingredients			
Ingredient Name			Strength
CAPRYLYL GLYCOL (UNII: 00YIU5438U)			
CHLORPHENESIN (UNII: I670DAL4SZ)			
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)			
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)			
POLYOXYL 40 HYDROGENATED CASTOR OIL (UNII: 7YC686GQ8F)			
PHENOXYETHANOL (UNII: HIE492ZZ3T)			
PIROCTONE OLAMINE (UNII: A4V5C6R9FB)			
POLYSORBATE 20 (UNII: 7T1F30V5YH)			
PPG-26-BUTETH-26 (UNII: 2II1K6TZ4P)			
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)			
ALCOHOL (UNII: 3K9958V90M)			
SODIUM HYDROXIDE (UNII: 55X04QC32I)			
WATER (UNII: 059QF0KO0R)			
Packaging			

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:79096-033-11	6 in 1 BOX	01/16/2023	
1		11 mL in 1 TUBE; Type 0: Not a Combination Product		
<b>Marketing Information</b>				
<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	01/16/2023	

**Labeler -** G.V. COSMETICS LTD (649551330)

## Establishment

Name	Address	ID/FEI	Business Operations
G.V. COSMETICS LTD		649551330	manufacture(79096-033)

Revised: 2/2023

G.V. COSMETICS LTD