

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

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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)

[Info@biotopworld.com](mailto:Info@biotopworld.com)

[www.biotopworld.com](http://www.biotopworld.com)

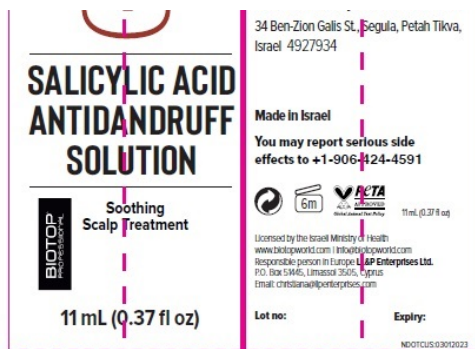
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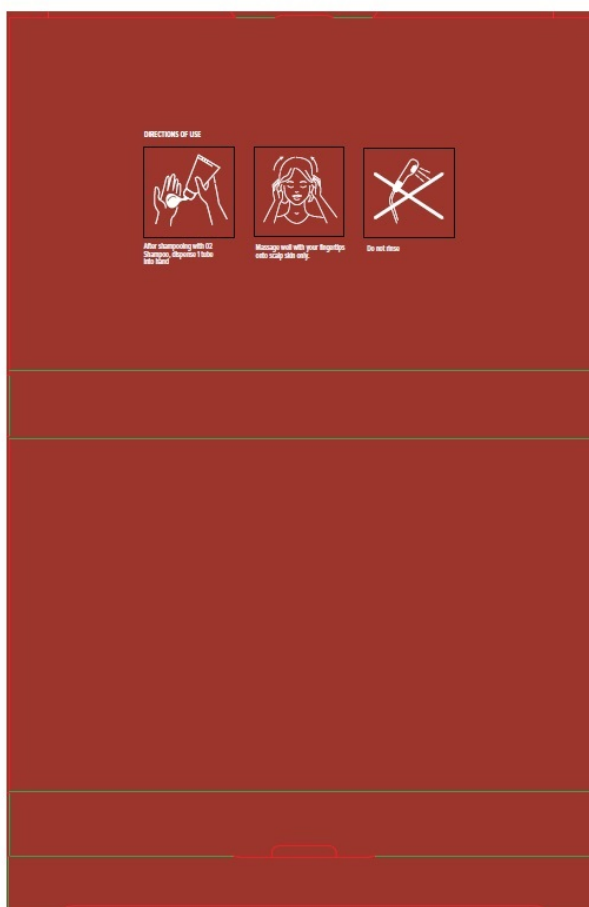
### **Packaging**

#### **INNER TUBE LABEL**





## OUTER BOX LABEL



## DRUG FACTS TABLE

Drug Facts	
Active ingredient	Purpose
Salicylic acid 1.8% w/v	Antidandruff
Use	
reduces the symptoms of dandruff	
Warnings	
For external use only	
<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>	
<b>When using this product</b> <ul style="list-style-type: none"> <li>do not get into eyes. In case of contact, rinse eyes thoroughly with water</li> </ul>	
<b>Stop use and ask a doctor if</b> <ul style="list-style-type: none"> <li>condition worsens or does not improve after regular use of this product as directed</li> <li>any irritation appears</li> </ul>	
<b>Keep out of reach of children.</b> If swallowed, get medical help or contact a Poison Control Center right away.	
Directions	
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your fingertips until dispersed fully and evenly

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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: H1E492ZZ3T)				
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	06/30/2025

1		11 mL in 1 TUBE; Type 0: Not a Combination Product		
Marketing Information				
Marketing Category	Application Number or Monograph Citation		Marketing Start Date	Marketing End Date
OTC Monograph Drug	M032		01/16/2023	06/30/2025

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

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