

**ALEVAI - ANTI DANDRUFF SCALP SERUM- zinc pyrithione cream**  
**ALEVAI PRODUCTS 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.*

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**81457-012-01**

**81457-012-02**

Zinc Pyrithione 0.12%

Anti-dandruff

**USES:**

For the relief of flaking and itching associated with dandruff.

For external use only.

Do not get into eyes. If contact occurs, rinse eyes thoroughly with water.

**STOP USE AND ASK DOCTOR IF**

condition worsens or does not improve after regular use of this product as directed.

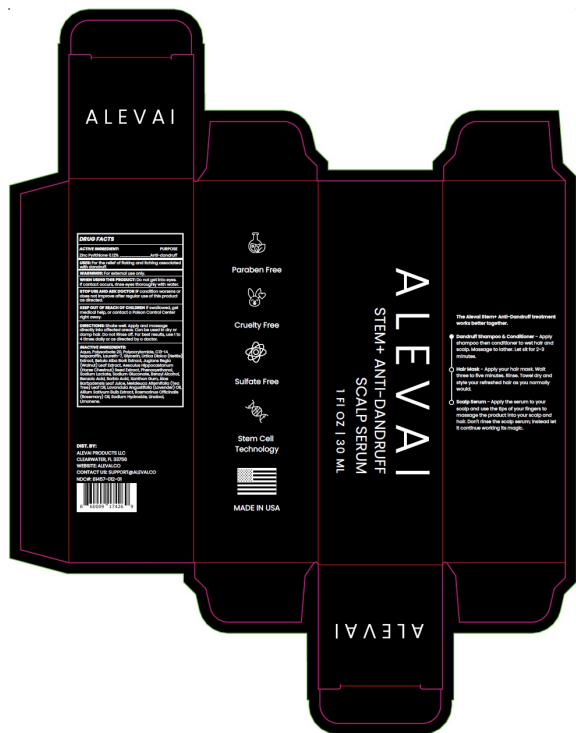
If swallowed, get medical help, or contact a Poison Control Center right away.

**DIRECTIONS:**

Shake well. Apply and massage directly into affected areas. Can be used in dry or damp hair. Do not Rinse off. For best results, use 1 to 4 times daily or as directed by a doctor.

Aqua, Polysorbate 20, Polyacrylamide, C13-14 Isoparaffin, Laureth-7, Glycerin, Urtica Dioica (Nettle) Extract, Betula Alba Bark Extract, Juglans Regia (Walnut) Leaf Extract, Aesculus Hippocastanum (Horse Chestnut) Seed Extract, Phenoxyethanol, Sodium Lactate, Sodium Gluconate, Benzyl Alcohol, Benzoic Acid, Sorbic Acid, Xanthan Gum, Aloe Barbadensis Leaf Juice, Melaleuca Alternifolia (Tea Tree) Leaf Oil, Lavandula Angustifolia (Lavender) Oil, Allium Sativum Bulb Extract, Rosmarinus Officinalis (Rosemary) Oil, Sodium Hydroxide, Linalool, Limonene.

**ALEVAI STEM + ANTI-DANDRUFF SCALP SERUM 1 FL OZ**



**ALEVAI STEM + ANTI-DANDRUFF SCALP SERUM 2 FL OZ**



## ALEVA I - ANTI DANDRUFF SCALP SERUM

zinc pyrithione cream

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:81457-012
<b>Route of Administration</b>	TOPICAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>PYRITHIONE ZINC</b> (UNII: R953O2RHZ5) (PYRITHIONE ZINC - UNII:R953O2RHZ5)	PYRITHIONE ZINC	0.12 g in 100 mL

### Inactive Ingredients

Ingredient Name	Strength
<b>SORBIC ACID</b> (UNII: X045WJ989B)	
<b>URTICA DIOICA LEAF</b> (UNII: X6M0DRN46Q)	
<b>BETULA PUBESCENS BARK</b> (UNII: 3R504894L9)	
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	

<b>WATER</b> (UNII: 059QF0KO0R)	
<b>POLYSORBATE 20</b> (UNII: 7T1F30V5YH)	
<b>C13-14 ISOPARAFFIN</b> (UNII: E4F12ROE70)	
<b>MELALEUCA ALTERNIFOLIA LEAF</b> (UNII: G43C57162K)	
<b>ALLIUM SATIVUM WHOLE</b> (UNII: IIF21WT8O3)	
<b>PHENOXYETHANOL</b> (UNII: HIE492ZZ3T)	
<b>ROSEMARY OIL</b> (UNII: 8LGU7VM393)	
<b>LINALOOL, (+/-)-</b> (UNII: D81QY6I88E)	
<b>LIMONENE, (+)-</b> (UNII: GFD7C86Q1W)	
<b>HORSE CHESTNUT</b> (UNII: 3C18L6RJAZ)	
<b>SODIUM LACTATE</b> (UNII: TU7HW0W0QT)	
<b>LAURETH-7</b> (UNII: Z95S6G8201)	
<b>XANTHAN GUM</b> (UNII: TTV12P4NEE)	
<b>SODIUM HYDROXIDE</b> (UNII: 55X04QC32I)	
<b>SODIUM GLUCONATE</b> (UNII: R6Q3791S76)	
<b>BENZYL ALCOHOL</b> (UNII: LKG8494WBH)	
<b>BENZOIC ACID</b> (UNII: 8SKN0B0MIM)	
<b>ALOE VERA LEAF</b> (UNII: ZY81Z83H0X)	
<b>JUGLANS REGIA LEAF</b> (UNII: 85HKB87105)	
<b>LAVENDER OIL</b> (UNII: ZBP1YXW0H8)	

### Product Characteristics

<b>Color</b>	white	<b>Score</b>	
<b>Shape</b>		<b>Size</b>	
<b>Flavor</b>		<b>Imprint Code</b>	
<b>Contains</b>			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:81457-012-01	1 in 1 BOX	04/17/2023	
1		30 mL in 1 BOTTLE, DROPPER; Type 0: Not a Combination Product		
2	NDC:81457-012-02	1 in 1 BOX	04/17/2023	
2		60 mL in 1 BOTTLE, DROPPER; Type 0: Not a Combination Product		

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	M032	04/17/2023	

**Labeler** - ALEVAI PRODUCTS LLC (117842557)

