

**ANTI DANDRUFF- salicylic acid shampoo**  
**Orange Lab**

*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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**Anti Dandruff Shampoo**

**Active Ingredient**

<b>DRUG FACTS</b>
<b>ACTIVE INGREDIENT:</b> Salicylic Acid 2 %
<b>PURPOSE:</b> Antidandruff

**Warnings**

<b>WARNINGS:</b> For external use only
Ask a doctor before use if you have
• seborrheic dermatitis in areas other than the scalp.
When using this product
• avoid contact with eyes. If contact occurs, rinse eyes thoroughly with water.
• for color-treated or permed hair, rinse thoroughly
Stop use and ask a doctor if
• condition worsens or does not improve after regular use of this product as directed

**Purpose**

<b>DRUG FACTS</b>
<b>ACTIVE INGREDIENT:</b> Salicylic Acid 2 %
<b>PURPOSE:</b> Antidandruff

**PREGNANCY OR BREAST-FEEDING**

Pregnancy Or Breast-feeding

• If pregnant or breast-feeding, ask a health professional before use.



## **KEEP OUT OF REACH OF CHILDREN**

Keep Out Of Reach Of Children

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

## **Inactive Ingredients**

### **INACTIVE INGREDIENTS:**

Aqua/Water, Sodium C14-16 Olefin Sulfonate, Cocamidopropyl Betaine, Disodium Laureth Sulfosuccinate, Sodium Lauryl Sulfoacetate, Glycol Stearate, Glycerin, Polyquaternium-10, Panthenol, Calendula Officinalis Flower Extract, Camellia Sinensis (Green Tea) Leaf Extract, Chamomilla Recutita (Matricaria) Flower Extract, Propolis Extract, Aloe Barbadensis Leaf Extract, Paullinia Cupana (Guarana) Seed Extract, Panax Ginseng Root Extract, Urtica Dioica (Nettle) Extract, Trimethylsiloxymethylmethicone, Menthol, Tocopheryl Acetate, Niacinamide, C12-16 Pareth-9, PPG-5-Ceteth-20, PEG-120 Methyl Glucose Dioleate, C11-15 Pareth-7, Trideceth-12, Benzyl Alcohol, Parfum(Fragrance), Dehydroacetic Acid, Benzoic Acid, Tetrasodium EDTA

## **Directions**

### **DIRECTIONS:**

Wet hair, massage a small amount on hair. Leave for 1 or 2 minutes and rinse thoroughly. Repeat if necessary. Great for all hair type, including color treated hair.

## **Shampoo description**

**ENFANTI ANTI-DANDRUFF SHAPOO** cleans hair eliminating flaking associated with dandruff. Fused with natural antiseptic herbs help ease psoriasis and dandruff, and conditioner hair and scalp.

**SULFATE FREE**

- Helps prevent itching and flaking
- Cools and refreshes the scalp
- Provides superior moisture
- Nourishes dry scalp

**Directions**

**DIRECTIONS:**

Wet hair, massage a small amount on hair. Leave for 1 or 2 minutes and rinse thoroughly. Repeat if necessary. Great for all hair type, including color treated hair.

**OTC Active Ingredient**

**DRUG FACTS**

**ACTIVE INGREDIENT:** Salicylic Acid 2 %

**PURPOSE:** Antidandruff

**USE:** AntiDandruff Shampoo is indicated for use in treatment of dandruff on hair and scalp.

**Principal Display Panel**

BIOKEN  
**ENFANTI**<sup>®</sup>  
NATURAL REMEDY



# ANTI-DANDRUFF SHAMPOO

DANDRUFF

32 FL.OZ.e(946ML)

## ANTI DANDRUFF

salicylic acid shampoo

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:71331-106
<b>Route of Administration</b>	TOPICAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>SALICYLIC ACID</b> (UNII: O414PZ4LPZ) (SALICYLIC ACID - UNII:O414PZ4LPZ)	SALICYLIC ACID	2 g in 100 g

### Inactive Ingredients

Ingredient Name	Strength
<b>EDETATE SODIUM TETRAHYDRATE</b> (UNII: L13NHD21X6)	
<b>MENTHOL</b> (UNII: L7T10EIP3A)	
<b>C12-16 PARETH-9</b> (UNII: 9DJ758090Y)	
<b>DEHYDROACETIC ACID</b> (UNII: 2KAG279R6R)	
<b>TRIDECETH-12</b> (UNII: YFY3KG5Y7O)	
<b>MATRICARIA RECUTITA</b> (UNII: G0R4UBI2ZZ)	
<b>COCAMIDOPROPYL BETAINE</b> (UNII: 5OCF3O11KX)	
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>ASIAN GINSENG</b> (UNII: CUQ3A77YXI)	
<b>BENZYL ALCOHOL</b> (UNII: LKG8494WBH)	
<b>SODIUM C14-16 OLEFIN SULFONATE</b> (UNII: O9W3D3YF5U)	
<b>ALOE VERA LEAF</b> (UNII: ZY81Z83H0X)	
<b>PEG-120 METHYL GLUCOSE DIOLEATE</b> (UNII: YM0K64F20V)	
<b>ALPHA-TOCOPHEROL ACETATE</b> (UNII: 9E8X80D2L0)	

<b>NIACINAMIDE</b> (UNII: 25X51I8RD4)
<b>PPG-5-CETETH-20</b> (UNII: 4AAN25P8P4)
<b>SODIUM LAURYL SULFOACETATE</b> (UNII: D0Y70F2B9J)
<b>PROPOLIS WAX</b> (UNII: 6Y8XYV2NOF)
<b>URTICA DIOICA LEAF</b> (UNII: X6M0DRN46Q)
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)
<b>PANTHENOL</b> (UNII: WW9CM0O67Z)
<b>POLYQUATERNIUM-10 (400 CPS AT 2%)</b> (UNII: HB1401PQFS)
<b>CALENDULA OFFICINALIS FLOWER</b> (UNII: P0M7O4Y7YD)
<b>DISODIUM LAURETH SULFOSUCCINATE</b> (UNII: D6DH1DTN7E)
<b>GLYCOL STEARATE</b> (UNII: 0324G66D0E)
<b>CAMELLIA SINENSIS WHOLE</b> (UNII: C5M4585ZBZ)
<b>PAULLINIA CUPANA SEED</b> (UNII: C21GE7524R)
<b>BENZOIC ACID</b> (UNII: 8SKN0B0MIM)
<b>C11-15 PARETH-7</b> (UNII: 261HPE0IS3)

### Product Characteristics

<b>Color</b>	white (Pearly White/Yellowish color)	<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:71331-106-09	237 g in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	01/01/2020	
2	NDC:71331-106-33	946 g in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	01/01/2020	

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	M032	01/01/2020	

**Labeler** - Orange Lab (004862271)

**Registrant** - Orange Lab (004862271)

### Establishment

Name	Address	ID/FEI	Business Operations
Orange Lab		004862271	manufacture(71331-106)