

**BIOELEMENTS IMMEDIATE COMFORT- hydrocortisone acetate lotion**  
**Bioelements, Inc.**

*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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**Immediate Comfort**

Active Ingredient Purpose

Hydrocortisone Acetate 1% Anti-itch lotion

Uses

For the temporary relief of itching associated with minor skin irritations and rashes due to exzema, detergents, cosmetics, jewelry, dermatitis, psoriasis.

Other uses of this product should be only under the advice and supervision of a doctor.

Keep out of reach of children. If swallowed get medical help or contact a poison control center right away.

Stop use and ask a doctor if condition worsens or symptoms persist for more than 7 days or clear up and occur again within a few days.

Warnings

For external use only

When using this product avoid contact with the eyes.

Directions

Apply to affected area no more than 3 to 4 times daily.

Inactive ingredients

Butylene Glycol, C12-15 Alkyl Benzoate, Carbomer, Glyceryl Stearate, Helianthus annus (sunflower) Seed Oil, Methylisothiazolinone, PEG-100 Stearate, Phenoxyethanol, Ploysorbate 80, Sodium Hydroxide, Sorbitol, Tocopheryl Acetate, Water (Aqua, Eau)

**Drug Facts**

**Active ingredient Purpose**  
Hydrocortisone Acetate 1%.....Anti-itch lotion

**Uses**

- For the temporary relief of itching associated with minor skin irritations and rashes due to eczema, detergents, cosmetics, jewelry, dermatitis, and psoriasis.
- Other uses of this product should be only under the advice and supervision of a doctor.

**Peel here for more Drug Facts**

**Drug Facts (continued)**

**Warnings**

**For external use only**

When using this product avoid contact with the eyes.

Stop use and ask a doctor if condition worsens, or symptoms persist for more than 7 days or clear up and occur again within a few days.

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

See inner label for additional Drug Facts

# BIOELEMENTS


PROFESSIONAL-USE-ONLY

## Immediate Comfort

1% Hydrocortisone Acetate Lotion

88 mL / 3 Fl. Oz.

Manufactured for BIOELEMENTS®  
3502 E. Boulder St.  
Colorado Springs, CO 80909  
Made in USA Bioelements.com  
SKU: PO622 / ART: 120604D



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Outer layer

**Drug Facts (continued)**

**Directions**

- Apply to affected areas no more than 3 to 4 times daily.

**Inactive ingredients**

Butylene Glycol, C12-15 Alkyl Benzoate, Carbomer, Glyceryl Stearate, Helianthus Annus (Sunflower) Seed Oil, Methylisithiazolinone, PEG-100 Stearate, Phenoxyethanol, Polysorbate 80, Sodium Hydroxide, Sorbitol, Tocopheryl Acetate, Water (Aqua, Eau)

**Other**

Store at 20-25 °C (68-77 °F) • Protect the product in this container from excessive heat and direct sun. Questions, call 1.800.433.6650 Monday - Friday 7:30AM - 4:30PM MST

Rounded area

Inner layer

Bioelements PROFESSIONAL-USE-ONLY  
 Immediate comfort  
 1% Hydrocortisone Acetate Lotion  
 88 ml / 3 Fl Oz.

BIOELEMENTS IMMEDIATE COMFORT			
hydrocortisone acetate lotion			
Product Information			
<b>Product Type</b>	HUMAN PRESCRIPTION DRUG	<b>Item Code (Source)</b>	NDC:49825-126
<b>Route of Administration</b>	TOPICAL		
Active Ingredient/Active Moiety			
<b>Ingredient Name</b>	<b>Basis of Strength</b>	<b>Strength</b>	
HYDROCORTISONE ACETATE (UNII: 3X7931PO74) (HYDROCORTISONE - UNII:W14X0X7BPJ)	HYDROCORTISONE ACETATE	0.088 mL in 88 mL	

## Inactive Ingredients

Ingredient Name	Strength
BUTYLENE GLYCOL (UNII: 3XUS85K0RA)	
ALKYL (C12-15) BENZOATE (UNII: A9EJ3J61HQ)	
CARBOMER HOMO POLYMER TYPE C (ALLYL PENTAERYTHRITOL CROSSLINKED) (UNII: 4Q93RCW27E)	
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	
SUNFLOWER OIL (UNII: 3W1JG795Y)	
METHYLISOTHIAZOLINONE (UNII: 229D0E1QFA)	
PEG-100 STEARATE (UNII: YD01N1999R)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
SORBITOL (UNII: 506T60A25R)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
WATER (UNII: 059QF0K00R)	

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:49825-126-01	88 mL in 1 BOTTLE		

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	08/23/2012	

**Labeler** - Bioelements, Inc. (174813923)

**Registrant** - Bioelements, Inc. (174813923)

## Establishment

Name	Address	ID/FEI	Business Operations
Dhaliwal Labs		016754201	manufacture(49825-126)