BIOELEMENTS IMMEDIATE COMFORT- hydrocortis one 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.

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

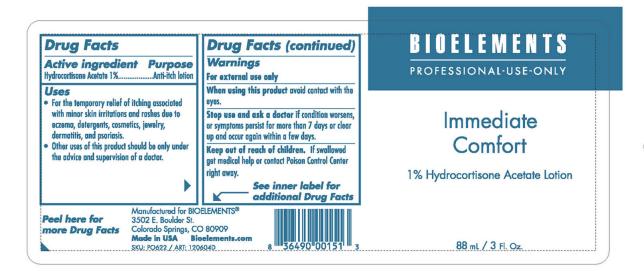
When using this product avoid contact with the eyes.

Directions

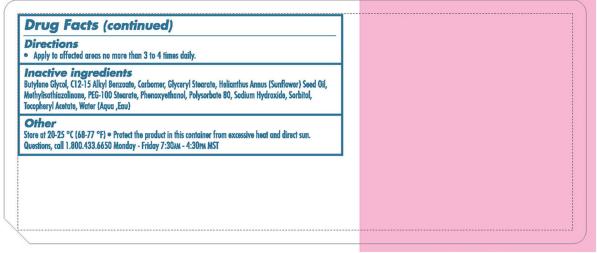
Apply to affected area no more than 3 to 4 times daily.

Inactive ingredients

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



Outer layer



Inner layer

Ronded area

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

BIOELEMENTS IMMEDIATE COMFORT

hydrocortisone acetate lotion

Product Information					
Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source) NDC:49825-126			
Route of Administration	TOPICAL				
Active Ingredient/Active Moi	ety				
	ety dient Name	Basis of Strer	ngth Strength		

Inactive Ingredients	
Ingredient Name	Strength
BUTYLENE GLYCOL (UNII: 3XUS85K0RA)	
ALKYL (C12-15) BENZOATE (UNII: A9EJ3J61HQ)	
CARBOMER HOMOPOLYMER TYPE C (ALLYL PENTAERYTHRITOL CROSSLINKED) (UNII: 4Q93RCW27E)	
GLYCERYL MONOSTEARATE (UNII: 230 OU9 XXE4)	
SUNFLOWER OIL (UNII: 3W1JG795YI)	
METHYLISOTHIAZOLINONE (UNII: 229 D0 E1QFA)	
PEG-100 STEARATE (UNII: YD01N1999R)	
PHENO XYETHANOL (UNII: HIE492ZZ3T)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
SORBITOL (UNII: 506T60A25R)	
.ALPHATO COPHERO L ACETATE (UNII: 9E8 X80 D2L0)	
WATER (UNII: 059QF0KO0R)	

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)	

Revised: 8/2012 Bioelements, Inc.