

ASTRINGENT- aluminum acetate gel
CA-BOTANA INTERNATIONAL

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.

Hydrogel Formulated with COSMEDERM7 For temporary Relief of Minor Itching and Burning

For external use only. Avoid contact with eyes. Keep out of reach of children. Do not apply to open wounds. STOP USE AND ask a doctor if condition worsens or symptoms persist for more than seven days, discontinue use of the product.

Adults and children two years of age and older, apply to affected area not more than three times daily or as directed by a doctor. Consult a physician for children under the age of two.

Butylene Glycol,
Caprylyl Glycol,
Dehydroacetic Acid,
Ethylhexylglycerin,
Glycine,
Hexylene Glycol,
Malic Acid,
Phenoxyethanol,
Purified Water,
Strontium Chloride Hexahydrate,
Xanthan Gum.

Astringent

1. Aluminium acetate

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aluminum acetate gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:35192-005
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALUMINUM ACETATE (UNII: 80EHD8I43D) (ALUMINUM CATION - UNII:3XHB1D032B)	ALUMINUM ACETATE	0.008 mg in 4 mL

Inactive Ingredients

Ingredient Name	Strength
Butylene Glycol (UNII: 3XUS85K0RA)	
Caprylyl Glycol (UNII: 00YIU5438U)	
Dehydroacetic Acid (UNII: 2KAG279R6R)	
Ethylhexylglycerin (UNII: 147D247K3P)	
Glycine (UNII: TE7660XO1C)	
Hexylene Glycol (UNII: KEH0A3F75J)	
Malic Acid (UNII: 817L1N4CKP)	

Phenoxyethanol (UNII: H1E492ZZ3T)	
Water (UNII: 059QF0KO0R)	
Strontium Chloride Hexahydrate (UNII: O09USB7Z44)	
Xanthan Gum (UNII: TTV12P4NEE)	

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:35192-005-04	4 mL in 1 POUCH		

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part347	01/01/2015	

Labeler - CA-BOTANA INTERNATIONAL (106276728)

Registrant - RODOLFO UGELSTAD (106276728)

Establishment			
Name	Address	ID/FEI	Business Operations
CA-BOTANA INTERNATIONAL		106276728	manufacture(35192-005)

Revised: 1/2015

CA-BOTANA INTERNATIONAL