

CORTISIL MDX- hydrocortisone acetate gel
BioZone Laboratories, 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.

Drug Facts

Active ingredient	Purpose
Hydrocortisone Acetate 1.0%	Anti-Pruritic

Use

For the temporary relief of itching associated with minor skin irritations, inflammation and rashes.

Warnings

For external use only

Do not use

- hydrocortisone product unless you have consulted a doctor.
- on children under 2 years of age.
- on mucous membranes

When using this product

- avoid contact with the eyes.
- If irritation develops, topical corticosteroids should be discontinued and appropriate therapy instituted.

Stop use and ask a doctor if

- condition worsens
- 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 a Poison Control Center immediately.

Directions

Adults and children 2 years of age and older: Apply to the affected area not more than 3 to 4 times daily.
Children under 2 year of age: consult a doctor.

Other information

Store at 15° to 30° C (59° to 86°F)

Carton: 1oz applicator pump

Inactive ingredients

Cyclopentasiloxane, Dimethicone Crosspolymer, Cyclomethicone, PEG-12 Glyceryl Dimyristate, Disodium EDTA.

Questions?

call 1-760-734-3622

PACKAGE LABEL.PRINCIPAL DISPLAY PANEL

NET WT. 30G NDC 55379-406-01

**CortiSIL™MDX
HYDROCORTISONE ACETATE 1% GEL**

**CONTAINS:
HYDROCORTISONE ACETATE 1% GEL
IN A NON-AQUEOUS SILICONE
AND SILICONE-CROSS POLYMER BASE.**

FOR EXTERNAL USE ONLY

Store: Room Temperature

US Patents: Pending

**MOKO
THERAPEUTICS LLC**

**Distributed By:
Moko Therapeutics LLC
Carlsbad, CA 92011**



CORTISIL MDX

hydrocortisone acetate gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:55379-406
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
HYDROCORTISONE ACETATE (UNII: 3X7931PO74) (HYDROCORTISONE - UNII:WI4X0X7BPJ)	HYDROCORTISONE ACETATE	1 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
CYCLOMETHICONE 5 (UNII: 0THT5PCI0R)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
CYCLOMETHICONE (UNII: NMQ347994Z)	
PEG-12 GLYCERYL DIMYRISTATE (UNII: VS4W16AQ3X)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:55379-406-01	1 in 1 CARTON		
1		30 g in 1 BOTTLE, PUMP		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part348	03/25/2013	

Labeler - BioZone Laboratories, Inc. (555564293)

Revised: 3/2013

BioZone Laboratories, Inc.