

**ZIMS ADVANCED CRACK CREME WITH HYDROCORTISONE- hydrocortisone cream
NATURAL ESSENTIALS, 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:

Hydrocortisone 1%

PURPOSE:

Anti-itch

USES:

Temporarily relieves itching associated with minor skin irritations

- inflammation and rashes due to:
 - eczema
 - psoriasis-poison ivy
 - oak
 - sumac
 - insect bites
 - detergents
 - jewelry
 - cosmetics
 - soaps
 - seborrheic
 - dermatitis
- Other uses of this product should be only under the advice and supervision of a doctor.

WARNINGS:

For external use only.

- When using this product avoid contact with the eyes
- do not use more than directed unless told to do so by a doctor
- do not put directly into the rectum by using fingers or any mechanical device or applicator

Stop use and ask a doctor if:

- condition worsens, symptoms persist for more than 7 days clears up and occur again within a few days
- do not begin use of any hydrocortisone product unless you have asked a doctor
- If rectal bleeding occurs

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

DIRECTIONS:

For Itching of Skin Irritation, Inflammation, and Rashes:

- Adults and Children 2 Years of Age and Older:
- Apply to affected area not more than 2 to 3 times daily.
- Children Under 2 Years of Age: Ask a doctor.
- For External Anal and Genital Itching, Adults:
- When practical, dean the affected area with mild soap and warm water and rinse thoroughly.
- Gently dry by patting or blotting with toilet tissue or a soft doth before applying.
- Apply to affected area not more than 2 to 3 times dally.
- Children Under 12 Years of Age: Ask a doctor.
- Store at 20-25 degrees C / 68-77 degrees F.

INACTIVE INGREDIENTS:

Water, Aloe Barbadosis Leaf Juice, SD Alcohol 3-C, Propylene Glycol, Cetearyl Alcohol, Isocetyl Stearate, Caprylic/Capric Triglyceride, Pimenta Acris (Bay) Leaf Oil, Isostearyl Palmitate, Cetyi Palmitate, Arnica Montana Flower Extract, Carbomer, Glyceryl Stearate, Ceteth-20, PEG-100 Stearate, Triethanolamine, Disodium EDTA, Methylparaben, Diazolidinyl Urea, Iodopropynyl Butylcarbamate.

Principal Display Panel - Tube Label

NEW!

ZIM'S®

ADVANCED

CRACK

CREME

Organic

ALOE AND

ARNICA

with HYDROCORTISONE

Dry, Cracked Skin

Rashes, Inflammation

Redness

Insect Bites

Eczema, Psoriasis

DEVELOPED BY A PHARMACIST

Net Wt 3 oz (85g)

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DO NOT USE IF SEAL IS BROKEN OR MISSING.

NDC 66902-228-03



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zimsusa.com

ZIMS ADVANCED CRACK CREME WITH HYDROCORTISONE

hydrocortisone cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:66902-228	
Route of Administration	TOPICAL			
Active Ingredient/Active Moiety				
Ingredient Name		Basis of Strength	Strength	
HYDROCORTISONE (UNII: WI4X0X7BPJ) (HYDROCORTISONE - UNII:WI4X0X7BPJ)		HYDROCORTISONE	10 mg in 1 L	
Inactive Ingredients				
Ingredient Name				Strength
ALOE VERA LEAF (UNII: ZY81Z83H0X)				
ARNICA MONTANA (UNII: O80TY208ZW)				
BAY LEAF OIL (UNII: 5UMH0U3W0V)				
CARBOMER HOMO POLYMER TYPE C (ALLYL PENTAERYTHRITOL CROSSLINKED) (UNII: 4Q93RCW27E)				
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)				
CETYL ALCOHOL (UNII: 936JST6JCN)				
WATER (UNII: 059QF0KO0R)				
DIAZOLIDINYL UREA (UNII: H5RIZ3MPW4)				
EDETATE DISODIUM (UNII: 7FLD91C86K)				
ALCOHOL (UNII: 3K9958V90M)				
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)				
IODOPROPYNYL BUTYL CARBAMATE (UNII: 603P14DHEB)				
ISOPROPYL MYRISTATE (UNII: 0RE8K4LNJS)				
ISOPROPYL PALMITATE (UNII: 8CRQ2TH63M)				
METHYL PARABEN (UNII: A2I8C7HI9T)				
PEG-100 STEARATE (UNII: YD01N1999R)				
POLYOXYL 20 CETOSTEARYL ETHER (UNII: YRC528SWUY)				
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)				
STEARYL ALCOHOL (UNII: 2KR89I4HIY)				
STEARYL PALMITATE (UNII: 214W90O2XZ)				
TROLAMINE (UNII: 9O3K93S3TK)				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:66902-228-03	1 in 1 TUBE		
1		0.00085 L in 1 TUBE		
Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph not final	part348	01/01/2014		

Labeler - NATURAL ESSENTIALS, INC. (947484713)

Establishment

Name	Address	ID/FEI	Business Operations
NATURAL ESSENTIALS, INC.		947484713	MANUFACTURE(66902-228)

Revised: 3/2014

NATURAL ESSENTIALS, INC.