HYDROCORTISONE - hydrocortisone cream CVS Pharmacy

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 1%...... Anti-itch cream

Uses

temporarily relieves itching associated with minor skin irritations, inflammation and rashes due to:

- eczema insect bites poison ivy, poison oak or poison sumac soaps detergents cosmetics
- jewlery seborrheic dermatitis psoriasis other uses of this product: ask a doctor

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

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Other information

- store at room temperature. Protect from freezing and excessive heat.
- see carton or tube crimp for lot number and expiration date.

Warnings

For external use only.

Do not use:

- in the eyes - for the treatment of diaper rash

Ask a doctor before use if you are using any other hydrocortisone product

Stop use and ask a doctor if

- condition worsens, or if symptoms persist for more than 7 days
- symptoms last 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 and older:apply to affected area not more than 3 to 4 times daily
- children under 2 years:do not use, ask a doctor

Inactive Ingredients

aloe barbadensis leaf juice, avena sativa kernal flour oat, beeswax, cetyl alcohol, citric acid, glyceryl stearate, isopropyl myristate, methylparaben, PEG-40 stearate, polysorbate 60, propylene glycol, propylparaben, purified water, sodium citrate, sodium stearate, sorbic acid, stearyl alcohol, tocopheryl acetate

Drug Facts



EFFECTIVE RELIEF FROM ITCHING while soothing irritated skin

Active ingredient Hydrocortisone 1% ...

Purpose

Uses

temporarily relieves itching associated with minor skin irritations, inflammation, and rashes due to:

• eczema • insect bites • poison ivy, poison oak or poison sumac • soaps • detergents • cosmetics • jewelry • seborrheic dermatitis • psoriasis • other uses of this product; ask a doctor

Warnings

For external use only

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• in the eyes • for the treatment of diaper rash

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NON-VARNISH



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EFFECTIVE RELIEF FROM ITCHING

Enriched with aloe and vitamin E WITH NATURAL COLLOIDAL OATMEAL

1% HYDROCORTISONE **MAJAD HOTI-ITUA** Maximum Strength

1% Hydrocortisone Anti-Itch Cream *Compare to the active ingredient in Aveeno*



bystmacy

(28.4g)

COLLOIDAL OATMEAL Enriched with aloe and vitamin E JARUTAN HTIW

CREAM 1% HYDROCORTIS Maximum Strength HDTI-ITNA

CA2

 detergents - soaps - cosmetics - jewelry · boison ivy · poison oak · poison sumac · insect bites eczema • psoriasis • seborrheic dermatitis RELIEVES ITCHING FROM INFLAMMATION AND RASHES CAUSED BY:

NET WT 1 OZ (28.4 g)

EFFECTIVE RELIEF FROM ITCHING

Enriched with aloe and vitamin E WITH NATURAL COLLOIDAL OATMEAL



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1% Hydrocortisone Anti-Itch Cream "Compare to the active ingredient in Aveeno"



HYDROCORTISONE

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:59779-322
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	Basis of Strength	Strength
HYDROCORTISONE (UNII: WI4X0 X7BPJ) (HYDROCORTISONE - UNII:WI4X0 X7BPJ)	HYDROCORTISONE	10 mg in 1 g

Inactive Ingredients		
Ingredient Name	Strength	
WATER (UNII: 059QF0KO0R)		
CETYL ALCOHOL (UNII: 936JST6JCN)		
GLYCERYL MONOSTEARATE (UNII: 230 O U9 XXE4)		
ISOPROPYL MYRISTATE (UNII: 0 RE8 K4LNJS)		
METHYLPARABEN (UNII: A2I8 C7HI9 T)		
POLYOXYL 40 STEARATE (UNII: 13A4J4NH9I)		
POLYSORBATE 60 (UNII: CAL22UVI4M)		
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)		
PROPYLPARABEN (UNII: Z8IX2SC1OH)		
ANHYDRO US TRISO DIUM CITRATE (UNII: RS7A450 LGA)		
SORBIC ACID (UNII: X045WJ989B)		
SODIUM STEARATE (UNII: QU7E2XA9TG)		
STEARYL ALCOHOL (UNII: 2KR89I4H1Y)		
.ALPHATO COPHEROL ACETATE, D- (UNII: A7E6112E4N)		
WHITE WAX (UNII: 7G1J5DA97F)		
OATMEAL (UNII: 8PI54V663Y)		
ANHYDRO US CITRIC ACID (UNII: XF417D3PSL)		
ALOE VERA LEAF (UNII: ZY81Z83H0 X)		

Packaging			
# Item Code	Package Description	Marketing Start Date	Marketing End Date
1 NDC:59779-322-20	1 in 1 CARTON		
1	28 g in 1 TUBE		

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	05/19/2009	

Labeler - CVS Pharmacy (062312574)

Registrant - Pharma Pac, LLC (140807475)

Establishment			
Name	Address	ID/FEI	Business Operations
Pharma Pac, LLC		140807475	manufacture

Revised: 2/2011 CVS Pharmacy