

ITCH RELIEF- hydrocortisone 1% cream
Trifecta Pharmaceuticals USA LLC

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.

CVS Health Itch Relief Cream

Drug Facts

Active Ingredient

Hydrocortisone 1%

Purpose

Anti-itch

Keep out of Reach of Children

If Swallowed, get medical help or contact a Poison Control Center right away.

Uses

For temporary relief of itching associated with minor skin irritations, inflammation and rashes due to

- Eczema
- Insect bites
- poison ivy
- poison oak
- poison sumac
- soaps
- detergents
- cosmetics
- jewelry
- seborrheic dermatitis
- psoriasis
- sunburn
- temporarily relieves external anal and genital itching.

Other uses of this product should be only under the advice and supervision of a doctor

Warnings

For External Use Only

Do not use

- In the genital area if you have a vaginal discharge.

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 rectum by using fingers or any mechanical device or applicator.

Stop Using this product and ask a doctor if

- Conditions worsen
- Symptoms persist for more than 7 days or clear up and occur again within a few days, and do not begin use of any other hydrocortisone product unless you have asked a doctor.
- Rectal bleeding occurs.

Directions

For itching or skin irritations, inflammation, and rashes.

Adults and children 2 years and older

- Apply to affected area not more than 3 to 4 times daily.

Children under 2 years of age

- ask a doctor.

For External and Anal Itching

- **Adults:** When practical, clean the affected area with mild soap and warm water and rinse thoroughly
- gently dry by patting or blotting with toilet tissue or a soft cloth before applying
- apply to affected area not more than 3 to 4 times daily
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- **Children under 12 years of age: ask a doctor**

Other Information

Store at controlled room temperature 20°-25°C (68°-77°F)

Inactive Ingredients

Aloe Barbadensis leaf juice, cetyl alcohol, Dimethicone, EDTA, Ethylparaben, Ginger Oil, Glycerin, Glyceryl stearate, Maltodextrin, Methyl gluceth-20, Methylparaben, Methylpentadecane, petrolatum, 2- Phenoxyethyl alcohol, Polysorbate 80, Propylene glycol, purified water, Stearic acid, Trisodium citrate dihydrate, Vitamin E.

Questions



ITCH RELIEF

hydrocortisone 1% cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:69396-057
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
HYDROCORTISONE (UNII: W4X0X7BPJ) (HYDROCORTISONE - UNII:W4X0X7BPJ)	HYDROCORTISONE	1 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
3-METHYLPENTADECANE (UNII: X64R3JC095)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
PHENOXYETHANOL (UNII: H1E492ZZ3T)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	
PETROLATUM (UNII: 4T6H12BN9U)	
WATER (UNII: 059QF0KO0R)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
TRISODIUM CITRATE DIHYDRATE (UNII: B22547B95K)	
.ALPHA.-TOCOPHEROL (UNII: H4N855PNZ1)	
GLYCERIN (UNII: PDC6A3C0OX)	

GINGER OIL (UNII: SAS9Z1SVUK)	
MALTODEXTRIN (UNII: 7CVR7L4A2D)	
CETYL ALCOHOL (UNII: 936JST6JCN)	
EDETIC ACID (UNII: 9G34HU7RV0)	
METHYL GLUCETH-20 (UNII: J3QD0LD11P)	
ETHYLPARABEN (UNII: 14255EXE39)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69396-057-01	1 in 1 BOX	09/17/2020	
1		28 g in 1 TUBE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	09/15/2020	

Labeler - Trifecta Pharmaceuticals USA LLC (079424163)

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Trifecta Pharmaceuticals USA LLC