

CVS HEALTH HYDROCORTISONE ANTI ITCH- hydrocortisone cream

CVS Health

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 1.0%

Purpose

Anti-itch

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
- external feminine, genital and anal 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

- for the treatment of diaper rash, consult a doctor.
- for external genital itching if you have a vaginal discharge, consult a doctor.

When using this product

- avoid contact with eyes
- do not begin the use of any other hydrocortisone product unless you have consulted a doctor.
- for external genital, feminine and anal itching do not exceed the recommended daily dosage unless directed by a doctor. In case of bleeding, stop use, consult a doctor.
- do not put this product into the rectum by using fingers or any mechanical device or applicator.

Stop use and ask a doctor if

- If condition worsens

- symptoms persist for more than 7 days or clear up and occur again within a few days, discontinue use of this product and do not begin use of any other hydrocortisone product unless directed by a doctor.

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

Directions

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

- do not use. Consult a doctor.

For external anal itching:

- adults: when practical cleanse the affected area with mild soap and warm water and rinse thoroughly or by patting or blotting with toilet tissue or a soft cloth before application of this product.
- children under 12 years of age with external anal itching: consult a doctor.

Other information

store at a controlled room temperature 20 - 25°C (68 - 77°F).

Inactive ingredients

Aloe barbadensis leaf extract, Aluminum Sulfate, Beeswax, Calcium acetate, Cetearly alcohol, Dextrin, Glycerin, Maltodextrin, Methylparaben, Mineral oil , Petrolatum, propylparaben, Sodium cetearyl sulfate, Sodium lauryl sulfate, Water (purified)

Principal Display Panel – Packet Label



103115

CVS Health NDC 69842-155-10

Cortisone MAXIMUM STRENGTH

Net Wt. 0.05 oz (1.5g) Hydrocortisone Cream USP 1%

Principal Display Panel – Carton Label



compare to the active ingredient in Cortisone 10[®]
 CVS Health NDC 69842-155-10
Cortisone MAXIMUM STRENGTH
 Net Wt. 1.2 oz (36g) Hydrocortisone Cream USP 1%

CVS HEALTH HYDROCORTISONE ANTI ITCH

hydrocortisone cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:69842-155
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Hydrocortisone (UNII: W14X0 X7BPJ) (Hydrocortisone - UNII:W14X0 X7BPJ)	Hydrocortisone	10 mg in 1g

Inactive Ingredients

Ingredient Name	Strength
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
ALUMINUM SULFATE (UNII: 34S289N54E)	

YELLOW WAX (UNII: 2ZA36H0S2V)	
CALCIUM ACETATE (UNII: Y882YXF34X)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	
GLYCERIN (UNII: PDC6A3C0OX)	
ICODextrin (UNII: 2NX48Z0A9G)	
MALTO Dextrin (UNII: 7CVR7L4A2D)	
METHYL PARABEN (UNII: A2I8C7HI9T)	
MINERAL OIL (UNII: T5L8T28FGP)	
PETROLATUM (UNII: 4T6H12BN9U)	
PROPYL PARABEN (UNII: Z8IX2SC1OH)	
SODIUM CETOSTEARYL SULFATE (UNII: 7ZBS06BH4B)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
WATER (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69842-155-10	24 in 1 CARTON	04/28/2017	
1		1.5 g in 1 PACKET; 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	04/28/2017	

Labeler - CVS Health (062312574)

Registrant - Sheffield Pharmaceuticals LLC (151177797)

Establishment

Name	Address	ID/FEI	Business Operations
Sheffield Pharmaceuticals LLC		151177797	MANUFACTURE(69842-155)