

HYDROCORTISONE- hydrocortisone cream

Valu Merchandisers, Co.

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

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

- eczema
- psoriasis
- seborrheic dermatitis
- poison ivy, oak, sumac
- insect bites
- soaps and detergents
- cosmetics
- jewelry
- external feminine and anal itching

Other uses of this product: ask a doctor

Warnings

For external use only

Do not use

- in or near the eyes
- by putting directly into the rectum by using fingers or any mechanical device or applicator
- for external feminine itching if you have a vaginal discharge
- for diaper rash: ask a doctor.

Ask a doctor or pharmacist before use if you are

using any other hydrocortisone product

When using this product

for external anal itching, do not exceed recommended daily dosage unless directed by a doctor

Stop use and ask a doctor if

- condition worsens or does not improve within 7 days
- symptoms clear up and return within a few days
- rectal bleeding occurs

Keep out of reach of children

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

Directions

- apply to affected area not more than 3 to 4 times daily
- for external anal itching: when practical, clean area with mild soap and warm water, rinse thoroughly, gently dry by patting or blotting with toilet tissue or a soft cloth before application of this product
- children under 2 years, or children under 12 years with external anal itching: do not use, ask a doctor

Other information

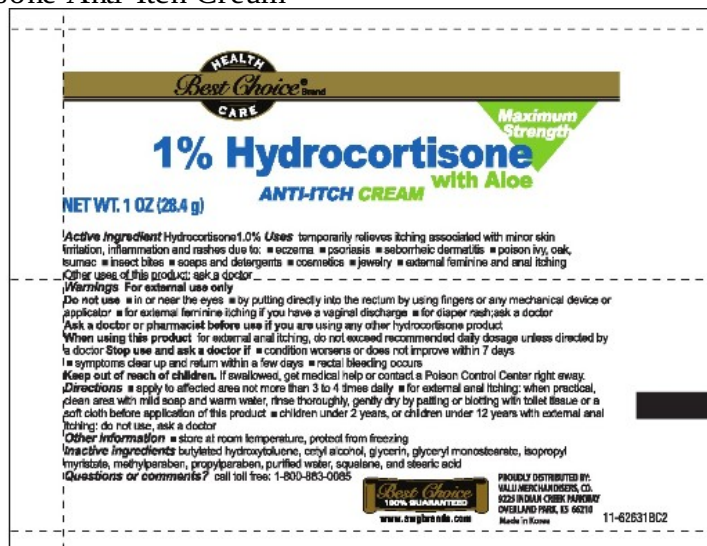
store at room temperature, protect from freezing

Inactive ingredients

butylated hydroxytoluene, cetyl alcohol, glycerin, glyceryl monostearate, isopropyl myristate, methylparaben, propylparaben, purified water, squalene, and stearic acid

Package label

Best Choice Hydrocortisone Anti-Itch Cream





HYDROCORTISONE

hydrocortisone cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:63941-312
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 g
Inactive Ingredients				
Ingredient Name				Strength
BUTYLATED HYDROXYTOLUENE (UNII: 1P9D0Z171K)				
CETYL ALCOHOL (UNII: 936JST6JCN)				
GLYCERIN (UNII: PDC6A3C0OX)				
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)				
ISOPROPYL MYRISTATE (UNII: 0RE8K4LNJS)				
METHYL PARABEN (UNII: A2I8C7HI9T)				
PROPYL PARABEN (UNII: Z8IX2SC1OH)				
WATER (UNII: 059QF0KO0R)				
SQUALENE (UNII: 7QWM220FJH)				
STEARIC ACID (UNII: 4ELV7Z65AP)				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:63941-312-01	1 in 1 BOX	02/29/2012	
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	02/29/2012	

Labeler - Valu Merchandisers, Co. (868703513)