

SUNMARK HYDROCORTISONE WITH ALOE MAXIMUM STRENGTH- hydrocortisone cream

Central Texas Community Health Centers

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.

Sunmark™ Hydrocortisone with Aloe Maximum Strength

Drug Facts

Active ingredient

Hydrocortisone 1%

Purpose

Anti-itch

Uses

for the temporary relief of itching associated with minor skin irritations, inflammation and rashes due to:

- eczema
- seborrheic dermatitis
- psoriasis
- insect bites
- poison ivy, oak, sumac
- soaps
- detergents
- cosmetics
- jewelry
- external 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**
- **avoid contact with the eyes**

Stop using this product and ask a doctor

- if condition worsens, or if symptoms persist for more than 7 days or clear up and occur again within a few days
- before you begin using any other hydrocortisone product

Do not use this product and ask a doctor

- if you have a vaginal discharge
- before treating diaper rash
- before using on children under 2 years of age

For External Anal Itching Users

- do not exceed the recommended daily dosage unless directed by a doctor
- in case of bleeding, consult a doctor promptly
- do not put this product into the rectum by using fingers or any mechanical device or applicator
- children under 12 years of age: consult a doctor

Keep this and all drugs out of the reach of children.

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

Before using any medication, read all label directions. Keep this carton. It contains important information.

Directions

- adults and children 2 years of age and older: apply to affected area not more than 3 to 4 times daily
- children under 2 years of age: do not use, ask a doctor

For External Anal Itching Users

- adults: when practical, cleanse 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 application of this product
- children under 12 years of age: consult a doctor

Other information

- unscrew cap, pull tab to remove foil seal, and screw cap back onto tube
- if seal has been broken, do not use this product. Return product to the store where you bought it.
- store at controlled room temperature 59°-86°F
- see carton or tube crimp for lot number and expiration date

Inactive ingredients

aloe barbadensis, cetostearyl alcohol, citric acid, glycerin, glyceryl stearate, methylparaben, mineral oil, paraffin, propylparaben, purified water, sodium cetearyl sulfate, sodium lauryl sulfate, stearyl alcohol

Distributed by McKesson
One Post Street
San Francisco, CA 94104

PRINCIPAL DISPLAY PANEL - 28.4 g Tube Carton

CommUnityCare Federally Qualified Health Centers

HYDROCORTISONE
1% CR 28g

Date:

Name:
Dr.

USE AS DIRECTED.

1/1/01

123456

HYDROCORTISONE 1% CRM 30G NDC 76413-334-28

Batch:
123456
Lot:
123456
Exp:
1/1/01
SUNMARK

Federal law prohibits the transfer of this drug to any other person than the patient for whom prescribed.

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SUNMARK HYDROCORTISONE WITH ALOE MAXIMUM STRENGTH

hydrocortisone cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:76413-334(NDC:49348-521)
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Hydrocortisone (UNII: WI4X0X7BPJ) (Hydrocortisone - UNII:WI4X0X7BPJ)	Hydrocortisone	1 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
aloe vera leaf (UNII: ZY81Z83H0X)	
cetostearyl alcohol (UNII: 2DMT128M1S)	
citric acid monohydrate (UNII: 2968PHW8QP)	

glycerin (UNII: PDC6A3C0OX)	
glyceryl monostearate (UNII: 230OU9XXE4)	
methylparaben (UNII: A2I8C7HI9T)	
mineral oil (UNII: T5L8T28FGP)	
paraffin (UNII: I9O0E3H2ZE)	
propylparaben (UNII: Z8IX2SC1OH)	
water (UNII: 059QF0KO0R)	
sodium cetostearyl sulfate (UNII: 7ZBS06BH4B)	
sodium lauryl sulfate (UNII: 368GB5141J)	
stearyl alcohol (UNII: 2KR89I4HIY)	

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:76413-334-28	1 in 1 BOX	08/23/1995	
1		28.4 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	08/23/1995	

Labeler - Central Texas Community Health Centers (079674019)

Establishment			
Name	Address	ID/FEI	Business Operations
Central Texas Community Health Centers		079674019	REPACK(76413-334) , RELABEL(76413-334)

Revised: 9/2017

Central Texas Community Health Centers