EQUALINE ANTI ITCH MAXIMUM STRENGTH- hydrocortisone cream United Natural Foods, Inc. dba UNFI

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.

SuperValu Inc. Anti-Itch Cream Drug Facts

Active ingredient

Hydrocortisone 1%

Purpose

Anti-itch

Uses

- temporarily relieves itching associated with minor skin irritations, inflammation, and rashes due to:
- eczema
- psoriasis
- poison ivy, oak, sumac
- insect bites
- detergents
- jewelry
- cosmetics
- soaps
- seborrheic dermatitis
- temporarily relieves external anal and genital itching
- other uses of this product should only be under the advice and supervision of a doctor

Warnings

For external use only

Do not use

- for the treatment of diaper rash. Ask a doctor.
- in the genital area if you have a vaginal discharge. Ask a doctor.

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 the rectum by using fingers or any mechanical device or applicator

Stop use and ask a doctor if

- condition worsens, 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

Keep out of reach of children.

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

Directions

- · for itching of skin irritation, inflammation, and rashes:
- 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 and genital 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
- children under 12 years of age: ask a doctor

Other information

store at 20°-25°C (68°-77°F)

Inactive ingredients

aloe barbadensis leaf juice, avena sativa (oat) kernel extract, benzyl alcohol, butylated hydroxytoluene, cetostearyl alcohol, cetyl alcohol, chamomilla recutita (matricaria) flower extract, diazolidinyl urea, dimethicone, distearyldimonium chloride, edetate disodium, glycerin, glyceryl monostearate, hydrolyzed collagen, hydrolyzed elastin, hydrolyzed jojoba esters, jojoba esters, magnesium ascorbyl phosphate, menthyl lactate, methyl gluceth-20, methylparaben, petrolatum, polysorbate 60, potassium hydroxide, PPG-12/SMDI copolymer, propylparaben, purified water, retinyl palmitate, stearamidopropyl PG-dimonium chloride phosphate, steareth-2, steareth-21, stearyl alcohol, tocopheryl acetate

Questions or comments?

1-855-423-2630

Principal Display Panel

EQUALINE®

compare to Cortizone • 10® active ingredient

helps heal itch fast

- clinically proven to moisturize 24 hours
- with chamomile & antioxidants vitamins A, C & E
- temporarily relieves dry, itchy skin, rashes, insect bites, eczema & psoriasis, inflammation, irritation & redness
- calms, nourishes, hydrates
- safe for sensitive skin

#1 doctor recommended itch relief active ingredient

EQUALINE®

compare to Cortizone•10® active ingredient

maximum strength

anti-itch cream

1% hydrocortisone anti-itch creme

intensive healing formula

NET WT 1 OZ (28g)

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#1 doctor recommended itch relief active ingredient*

ultra creamy formula helps heal problem skin

EQUALINE®

NDC 41163-369-64

compare to

maximum strength

anti-itch cream

1% hydrocortisone anti-itch creme

intensive healing formula

NETWT1 OZ (28g)



36964 EL C5

EQUALINE®



Drug Facts

Active ingredient

Uses

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Drug Facts (continued)

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Questions or comments?1 455-4232630

*This product is not man ufacture dor distributed by Chattern, Inc., own er of the registered trademak Contzone • 10 @.

♦h the U.S. Source: Symphony Health Solutions

Distributed by UNFL Providence, RI 02908 USA

100% Quality GUARANTEED

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hydrocortisone cream

Product Information

Product Type HUMAN OTC DRUG NDC:41163-369 **Item Code (Source)**

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	
ALOE VERA LEAF (UNII: ZY81Z83H0X)		
OAT (UNII: Z 6J799EAJK)		
BENZYL ALCOHOL (UNII: LKG8494WBH)		
BUTYLATED HYDROXYTOLUENE (UNII: 1P9D0Z171K)		
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)		
CETYL ALCOHOL (UNII: 936JST6JCN)		
CHAMOMILE (UNII: FGL3685T2X)		
DIAZOLIDINYL UREA (UNII: H5RIZ3MPW4)		
DIMETHICONE (UNII: 92RU3N3Y1O)		
DISTEARYLDIMONIUM CHLORIDE (UNII: OM9573ZX3X)		
EDETATE DISODIUM (UNII: 7FLD91C86K)		
GLYCERIN (UNII: PDC6A3C0OX)		
GLYCERYL MONOSTEARATE (UNII: 2300U9XXE4)		
HYDROLYZED JOJOBA ESTERS (ACID FORM) (UNII: UDR641JW8W)		
MAGNESIUM ASCORBYL PHOSPHATE (UNII: 0R822556M5)		
MENTHYL LACTATE, (-)- (UNII: 2BF9E65L7I)		
METHYL GLUCETH-20 (UNII: J3QD0LD11P)		
METHYLPARABEN (UNII: A2I8C7HI9T)		
PETROLATUM (UNII: 4T6H12BN9U)		
POLYSORBATE 60 (UNII: CAL22UVI4M)		
POTASSIUM HYDROXIDE (UNII: WZH3C48M4T)		
PROPYLPARABEN (UNII: Z8IX2SC10H)		
WATER (UNII: 059QF0KO0R)		
VITAMIN A PALMITATE (UNII: 1D1K0N0VVC)		
STEARETH-2 (UNII: V56DFE46J5)		

STEARAMIDOPROPYL PROPYLENE GLYCOL-DIMONIUM CHLORIDE PHOSPHATE (UNII: W6000VEI5Y)

PPG-12/SMDI COPOLYMER (UNII: 1BK9DDD24E)

.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)

HYDROLYZED BOVINE ELASTIN (BASE; 1000 MW) (UNII: ZR28QKN0WT)

Product Characteristics

STEARETH-21 (UNII: 53J3F32P58) STEARYL ALCOHOL (UNII: 2KR89I4H1Y)

Color	WHITE (Off white)	Score
Shape		Size
Flavor		Imprint Code
Contains		

Packaging			
# Item Code	Package Description	Marketing Start Date	Marketing End Date

1 NDC:41163-369-64 1 in 1 CARTON
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	02/25/2011			

02/25/2011

Labeler - United Natural Foods, Inc. dba UNFI (943556183)

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