

NATUREPLEX HYDROCORTISONE HYDRO- hydrocortisone cream

Natureplex, 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.

Hydrocortisone Cream

Drug Facts

Active ingredient

Hydrocortisone 1%

Purpose

Antipruritic (anti-itch)

Uses

- for the 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
- and for external anal and genital itching

Warnings

For external use only.

Avoid contact with eyes.

Do Not Use

- if you have a vaginal discharge. Consult a doctor.

When using this product

- do not exceed the recommended daily dosage unless directed by a doctor
- do not put 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
- bleeding occurs

If pregnant or breast-feeding, ask a health professional before use.

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away: 800-222-1222.

Directions

For itching associated with minor skin irritations, 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: Consult a doctor

For external anal and genital itching:

Adults and children 12 years of age and older:

- when practical, cleanse the affected area with mild soap or warm water and rinse thoroughly or by patting or blotting with an appropriate cleansing pad
- gently dry by patting or blotting with toilet tissue or a soft cloth before application of this product
- apply to affected area not more than 3 to 4 times daily

Children under 12 years of age: Consult a doctor

Other information

- store at 15 to 30°C (59 to 86°F)
- **Tamper Evident:** DO NOT USE IF SEAL ON TUBE IS BROKEN OR MISSING.

Inactive ingredients

aloe barbadensis leaf juice, carbomer, cetyl alcohol, DMDM hydantoin, glyceryl stearate, isopropyl alcohol, methylparaben, mineral oil, polysorbate-20, propylparaben, purified water, stearic acid, triethanolamine, trisodium EDTA

Questions or comments?

866-323-0107 or www.natureplex.com

PRINCIPAL DISPLAY PANEL - 28 g Tube Carton

Natureplex™

MAXIMUM STRENGTH

Hydrocortisone Cream

Fast Itch And Rash Relief!

NET WT. 1 Oz. (28g)

Natureplex™

NDC 67234-010-01

Hydrocortisone Cream

Fast Itch And Rash Relief!

* Compare to the active ingredients of Cortaid®

- Eczema • Psoriasis • Seborrheic Dermatitis
- Soaps • Insect Bites • Poison Ivy, Oak & Sumac • And More



Relief In A Soothing & Cooling Cream



20598
V116

Natureplex™
Hydrocortisone Cream

Natureplex™

MAXIMUM STRENGTH

Hydrocortisone Cream

Fast Itch And Rash Relief!

NET WT. 1 Oz. (29g)

MAXIMUM STRENGTH

Hydrocortisone Cream



*This product is not manufactured by or distributed by Pharmacia Consumer Healthcare, the distributor of Cortaid®.

NATUREPLEX, Olive Branch, MS 38654

MADE IN THE USA

Natureplex™

Drug Facts	<p>Active ingredient Hydrocortisone 1%.....Antipruritic (anti-itch)</p> <p>Uses • for the temporary relief of itching associated with minor skin irritations, inflammations, and rashes; • bites, poison ivy, poison oak, poison sumac, soaps, detergents, cosmetics, jewelry • and for external anal and genital itching</p> <p>Warnings For external use only. Avoid contact with eyes.</p> <p>Do Not Use • If you have a vaginal discharge. Consult a doctor. When using this product • do not exceed the recommended daily dosage unless directed by a doctor • do not put 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 • bleeding occurs If pregnant or breast-feeding, ask a health professional before use. Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away. 800-222-1222</p>
Drug Facts (continued)	
Purpose	For itching associated with minor skin irritations, inflammations, and rashes.
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: Consult a doctor. For external anal and genital itching: Adults and children 12 years of age and older: when practical, cleanse the affected area with mild soap or warm water and rinse thoroughly or by patting or blotting with an appropriate cleansing pad gently dry by patting or blotting with toilet tissue or a soft cloth before application of this product apply to affected area not more than 3 to 4 times daily
Other information	• store at 15 to 30 °C (59 to 86 °F) • Tamper Evident: DO NOT USE IF SEAL ON TUBE IS BROKEN OR MISSING.
Inactive ingredients	aloe barbadensis leaf juice, catnip, cetyl alcohol, DMDM hydantoin, glyceryl stearate, isopropyl alcohol, methylparaben, mineral oil, polysorbate-20, propylparaben, purified water, stearyl alcohol, triethanolamine, triiodium EDTA
Questions or comments?	866-323-0107 or www.natureplex.com

MAXIMUM STRENGTH

Natureplex™
Hydrocortisone Cream

NATUREPLEX HYDROCORTISONE HYDRO

hydrocortisone cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:67234-010
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Hydrocortisone (UNII: W14X0X7BPJ) (Hydrocortisone - UNII:W14X0X7BPJ)	Hydrocortisone	0.01 g in 1 g

Inactive Ingredients

Ingredient Name	Strength
Aloe Vera Leaf (UNII: ZY81Z83H0X)	
CARBOMER HOMO POLYMER TYPE C (ALLYL PENTAERYTHRITOL CROSSLINKED) (UNII: 4Q93RCW27E)	
cetyl alcohol (UNII: 936JST6JCN)	
DMDM Hydantoin (UNII: BYR0546TOW)	
glyceryl monostearate (UNII: 230OU9XXE4)	
methylparaben (UNII: A218C7H9T)	
mineral oil (UNII: T5L8T28FGP)	
polyorbate 20 (UNII: 7T1F30V5YH)	
propylparaben (UNII: Z8IX2SC1OH)	
stearic acid (UNII: 4ELV7Z65AP)	
trolamine (UNII: 9O3K93S3TK)	
edetate trisodium (UNII: 420IP921MB)	
water (UNII: 059QF0KO0R)	
alcohol (UNII: 3K9958V90M)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:67234-010-01	28 g in 1 TUBE; Type 0: Not a Combination Product	01/22/2008	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	01/22/2008	

Labeler - Natureplex, LLC (062808196)

Establishment

Name	Address	ID/FEI	Business Operations
Natureplex, LLC		062808196	manufacture(67234-010)

