

HYDROCORTISONE - hydrocortisone acetate cream

Choice Laboratories

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 1%

Active Ingredient	Purpose
Hydrocortisone Acetate 1%	Antipruritic (anti-itch)

Uses:

For temporary relief of;

- minor skin irritations

Itching and rashes due to;

- eczema
- insect bites
- poison ivy
- poison oak
- poison sumac
- soaps
- detergents
- cosmetics
- jewelry

and for external itching of;

- genital
- feminine and
- anal itching

Warnings:

For external use only

Do not use:

- in the eyes
- longer than 1 week unless directed by a physician
- for diaper rash
- if you have vaginal discharge
- more than the recommended daily dosage unless directed by a doctor
- in the rectum bu using fingers or any other mechanical device or applicator

Stop use and ask a physician if:

- the condition persists or gets worse
- symptoms clear up and occur again within a few days
- you are pregnant or breast feeding

Keep out of reach of children

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

Directions:

Adults and children over 2 years of age

- Apply evenly to affected area no more than 3 or 4 times daily.

Children under 2 years of age

- Do not use
- consult a physician

Adults

- When practical, cleanse the affected area with mild soap and warm water and rinse thoroughly
- Gently dry, patting and blotting with bathroom tissue or soft cloth before applying
- apply externally to the area up to 6 times daily or after each bowel movement

Other information:



- Store at 20 deg - 25 deg C (68 deg - 77 deg F)
- Avoid excessive heat and humidity

Inactive ingredients:

Citric acid, Glycerin, Glycerol stearate, Methylparaben, Petrolatum, Polysorbate 80, Propylene Glycol, Propylparaben, Sodium citrate, Titanium dioxide, Water (purified)

Principal Display Panel


Hydrocortisone Cream 1%

<p>Drug Facts</p> <p>Active ingredient Hydrocortisone Acetate 1%.....Purpose Antipruritic (Anti-Itch)</p> <p>Uses: For temporary relief of minor skin irritations, itching and rashes due to eczema, insect bites, poison ivy, poison oak, poison sumac, soaps, detergents, cosmetics, jewelry and for external genital, feminine and anal itching.</p> <p>Warnings • For External Use Only When using this product Do not get into eyes</p> <p>Stop use and ask a physician if:</p> <ul style="list-style-type: none"> • the condition persists or gets worse • symptoms clear up and occur again within a few days • you are pregnant or breast-feeding <p>Do not use:</p> <ul style="list-style-type: none"> • in the eyes • longer than 1 week unless directed by a physician • for diaper rash • if you have vaginal discharge • more than the recommended daily dosage unless directed by a doctor • in the rectum by using fingers or any mechanical device or applicator. 	<p>Drug Facts (continued)</p> <p>Keep out of reach of children If swallowed, get medical help or contact a Poison Control Center right away.</p> <p>Directions:</p> <ul style="list-style-type: none"> • Adults and children over 2 years of age • Apply evenly to affected area no more than 3 to 4 times daily. • Children under 2 years of age • Do not use. Consult a doctor. • Adults • When practical, cleanse the affected area with mild soap and warm water and rinse thoroughly • Gently dry, patting or blotting with bathroom tissue or soft cloth before applying. • Apply externally to the area up to 6 times daily or after each bowel movement. <p>Other information</p> <ul style="list-style-type: none"> • Store at 20°-25° C (68°-77° F) • Avoid excessive heat and humidity <p>Inactive ingredients: Citric acid, glycerin, glycerol stearate, methyl paraben, petrolatum, polysorbate 80, propylene glycol, propyl paraben, purified water, sodium citrate and titanium dioxide.</p>	 <p>Hydrocortisone 1% Relief of Minor Skin Irritations, Itching and Rashes</p> <p>15 ounces</p> <p>Reorder No. 1139 Made in India</p>	<p>Manufactured for: Dynarex Corporation Orangeburg, NY 10962 www.dynarex.com</p> <p>NDC # 67777-224-08</p> 
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Hydrocortisone Cream 1%
Relief of Minor Skin Irritations, Itching and rashes

Reorder No. 1138 Net Wt. 1 OZ (28.4g)

<p>Drug Facts</p> <p>Active ingredient Hydrocortisone Acetate 1%.....Purpose Antipruritic (Anti-Itch)</p> <p>Uses: For temporary relief of minor skin irritations, inflammation and rashes due to eczema, insect bites, poison ivy, poison oak, or poison sumac, soaps, detergents, cosmetics, jewelry and for external genital, feminine and anal itching.</p> <p>Warnings For external use only.</p> <p>Do not use • in the eyes • for diaper rash • if you have vaginal discharge • more than recommended dosage Ask a doctor before use if you are pregnant or breast-feeding.</p>	<p>Drug Facts (continued)</p> <p>Warnings (continued) Stop use and ask a doctor if • the condition worsens, or if symptoms persist for more than 7 days or clear up and occur again within a few days</p> <p>Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.</p> <p>Important: • See pamphlet inside box for complete Drug Facts, Directions and additional information.</p>	<p>Manufactured for: Dynarex Corporation Orangeburg, NY 10962 www.dynarex.com</p> <p>Made in India</p>  <p>NDC 66777-224-01 6 16784 11381 4</p>
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DRUG FACTS	Purpose
ACTIVE INGREDIENTS Hydrocortisone Acetate 1%.....	Antipruritic - (Anti-Itch)
USES • For temporary relief of minor skin irritations, itching and rashes due to eczema, insect bites, poison ivy, poison oak, poison sumac, soaps, detergents, cosmetics, jewelry and for external genital, feminine and anal itching.	
WARNING: For external use only	
Do not use: • In the eyes • longer than 1 week unless directed by a physician • for diaper rash • if you have vaginal discharge • more than the recommended daily dosage unless directed by a doctor • in the rectum by using fingers or any mechanical device or applicator.	
Stop use and ask a physician if: • the condition persists or gets worse • symptoms clear up and occur again within a few days • you are pregnant or breast-feeding	
KEEP OUT OF REACH OF CHILDREN. If swallowed, get medical help or contact a Poison Control Center right away.	
DIRECTIONS:	
• Adults and children over 2 years of age • Apply evenly to affected area no more than 3 to 4 times daily.	
• Children under 2 years of age • Do not use. Consult a doctor.	
• Adults • When practical, cleanse the affected area with mild soap and warm water and rinse thoroughly • Gently dry, patting or blotting with bathroom tissue or soft cloth before applying • Apply externally to the area up to 6 times daily or after each bowel movement.	
OTHER INFORMATION: • Store at 20°-25° C (68°-77° F) • Avoid excessive heat and humidity	
INACTIVE INGREDIENTS: Citric acid, Glycerin, Glycerol stearate, Methyl paraben, Petrolatum, Polysorbate 80, Propylene glycol, Propyl paraben, Purified water, Sodium citrate and Titanium dioxide.	

HYDROCORTISONE

hydrocortisone acetate cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:63174-224
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
HYDROCORTISONE ACETATE (UNII: 3X7931PO74) (HYDROCORTISONE - UNII:W14X0X7BPJ)	HYDROCORTISONE ACETATE	1 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
GLYCERIN (UNII: PDC6A3C0OX)	
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
PETROLATUM (UNII: 4T6H12BN9U)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SODIUM CITRATE (UNII: 1Q73Q2JULR)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
WATER (UNII: 059QF0K00R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:63174-224-01	72 in 1 CASE		
1		28.3 g in 1 TUBE		
2	NDC:63174-224-08	12 in 1 CASE		
2		425 g in 1 JAR		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part348	02/02/2010	

Labeler - Choice Laboratories (650070394)

Establishment

Name	Address	ID/FEI	Business Operations
Choice Laboratories		650070394	manufacture

Revised: 2/2010

Choice Laboratories