

HYDROCORTISONE- hydrocortisone cream

Padagis Israel Pharmaceuticals Ltd

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.

Perrigo Hydrocortisone Cream 1% Drug Facts

Active ingredient

Hydrocortisone 1%

Purpose

Anti-itch

Uses

- temporarily relieves itching associated with minor skin irritations, inflammation, and rashes due to:
 - eczema
 - insect bites
 - poison ivy, oak, or sumac
 - soaps
 - detergents
 - cosmetics
 - jewelry
 - seborrheic dermatitis
 - psoriasis
- 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

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

When using this product

- avoid contact with 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 (1-800-222-1222).

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: ask a doctor
- **for external anal and genital itching, 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 applying
- apply to affected area not more than 3 to 4 times daily
- children under 12 years of age: ask a doctor

Inactive ingredients

water, cetearyl alcohol, cetareth-20, cetyl palmitate, glycerin, isopropyl myristate, isostearyl neopentanoate, methylparaben, aloe barbadensis leaf juice

Questions or comments?

1-800-719-9260

Principal Display Panel

Compare to Cortaid® active ingredient

Hydrocortisone Cream 1%

Anti-Itch Cream Maximum Strength

NET WT 1 LB (454 g)

Perrigo®

Compare to Cortaid®
active ingredient

NDC 45802-438-05

Hydrocortisone Cream

1%

Anti-Itch Cream
Maximum Strength

NET WT 1 LB (454 g)



N 3 45802-438-05 8

Drug Facts

Active ingredient Hydrocortisone 1%
Purpose Anti-itch

Uses ■ temporarily relieves itching associated with minor skin irritations, inflammation, and rashes due to: ■ eczema ■ insect bites ■ poison ivy, oak, or sumac ■ soaps ■ detergents ■ cosmetics ■ jewelry ■ seborrheic dermatitis ■ psoriasis ■ 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 ■ in the genital area if you have a vaginal discharge. Consult a doctor. ■ for the treatment of diaper rash. Consult a doctor.

When using this product ■ avoid contact with 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

Drug Facts (continued)

you have asked a doctor ■ rectal bleeding occurs
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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: ask a doctor ■ for external anal and genital itching, 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 applying ■ apply to affected area not more than 3 to 4 times daily ■ children under 12 years of age: ask a doctor

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Questions or comments? 1-800-719-9260

Store at 20-25°C (68-77°F).

Distributed By Perrigo
Allegan, MI 49010
www.perrigo.com

: 54167 RT F5



HYDROCORTISONE

hydrocortisone cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:45802-438
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
WATER (UNII: 059QF0KO0R)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	
POLYOXYL 20 CETOSTEARYL ETHER (UNII: YRC528SWUY)	
CETYL PALMITATE (UNII: 5ZA2S6B08X)	
GLYCERIN (UNII: PDC6A3C0OX)	
ISOPROPYL MYRISTATE (UNII: 0RE8K4LNJS)	
ISOSTEARYL NEOPENTANOATE (UNII: 411THY156Q)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	

Product Characteristics

Color	WHITE	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:45802-438-03	1 in 1 CARTON	05/06/2011	
1		28 g in 1 TUBE; Type 0: Not a Combination Product		
2	NDC:45802-438-05	1 in 1 CARTON	05/10/2011	
2		454 g in 1 JAR; Type 0: Not a Combination Product		
3	NDC:45802-438-70	144 in 1 CARTON	09/01/2011	09/16/2015
3		.9 g in 1 PACKET; 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	04/13/2011	

Labeler - Padagis Israel Pharmaceuticals Ltd (600093611)

Revised: 11/2021

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