

HYDROCORTISONE- hydrocortisone cream

A-S Medication Solutions

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

HOW SUPPLIED

Product: 50090-4094

NDC: 50090-4094-0 28 g in a TUBE / 1 in a CARTON

HYDROCORTISONE CREAM

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

Patient First®

WARNING: KEEP OUT OF CHILDREN'S REACH. DISPENSE IN THIS LIGHT RESISTANT CONTAINER.

STORE AT 68-77 DEGREES F



GTIN: 00350090409406
 LOT:
 EXP:
 S/N:

Packaged Exclusively By:
A-S MEDICATION SOLUTIONS LLC™
 Libertyville, IL 60048

AFFIX LABEL HERE

**HYDROCORTISONE
 MAXIMUM STRENGTH 1 %**

144 TUBES PER CASE, EACH 1 OZ (28G)
 ANTI-ITCH CREAM
 NDC 50090-4094-0
 PRODUCT # 8383-0

ACTIVE INGREDIENT
 HYDROCORTISONE 1 %
 PURPOSE: ANTI-ITCH

MFR: L. PERRIGO COMPANY
 ALLEGAN, MI 49010
 SRC NDC: 45802-438-03

LOT#

AFFIX LABEL HERE



HYDROCORTISONE

hydrocortisone cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:50090-4094(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:50090-4094-0	1 in 1 CARTON	01/25/2019	
1		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	04/13/2011	

Labeler - A-S Medication Solutions (830016429)

Establishment

Name	Address	ID/FEI	Business Operations
A-S Medication Solutions		830016429	RELABEL(50090-4094)

Revised: 3/2021

A-S Medication Solutions