

HYDROCORTISONE- hydrocortisone 1% ointment
Weeks & Leo Co., Inc.

Hydrocortisone Ointment

Active ingredient

Hydrocortisone 1%

Purpose

Anti-itch

Uses

For the temporary relief of itching associated with minor skin irritations, inflammation, and rashes due to:

- eczema
- seborrheic dermatitis
- poison ivy, poison oak, and poison sumac
- psoriasis
- insect bites
- cosmetics
- jewelry
- detergents
- soaps

temporarily relieves external anal and genital itching

other uses of this product should be only under the advise and supervision of a doctor

Warnings

For external use only

Do not use

- for the treatment of diaper rash. Ask a doctor.
- for external genital itching if you have a vaginal discharge. Ask a doctor.
- for external anal itching if rectal bleeding occurs. Consult a doctor promptly.

When using this product

- do not get in the eyes
- for external anal itching, do not use more than directed unless told to do so 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 gets worse, or if symptoms last for more than 7 days or clear up and occur again within a few days. Do not begin use of any other hydrocortisone product.

Keep out of reach of children.

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

Directions

adults and children 2 years and over: apply to affected area not more than 3 to 4 times daily

children under 2 years: ask a doctor

for external anal itching in adults:

- when practical, cleanse the affected area with mild soap and 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 applying

for external anal itching in children under 12 years: ask a doctor

Other information

- store at 20°C to 25°C (68°F to 77°F)

Inactive ingredient

white petrolatum



HYDROCORTISONE

hydrocortisone 1% ointment

Product Information

Product Type

HUMAN OTC DRUG

Item Code (Source)

NDC:11383-268

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	
WHITE PETROLATUM (UNII: B6E5W8RQJ4)				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:11383-268-01	28 g in 1 TUBE; Type 0: Not a Combination Product	10/01/2023	
2	NDC:11383-268-02	59 g in 1 TUBE; Type 0: Not a Combination Product	10/01/2023	
Marketing Information				
Marketing Category		Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug		M017	10/01/2023	

Labeler - Weeks & Leo Co., Inc. (005290028)

Establishment			
Name	Address	ID/FEI	Business Operations
Weeks & Leo Co., Inc.		005290028	manufacture(11383-268)

Revised: 12/2023

Weeks & Leo Co., Inc.