

ANTI-ITCH PARABEN FREE- hydrocortisone cream
Weeks & Leo Co., Inc.

Hydrocortisone Paraben Free

Active Ingredient

Hydrocortisone 1 %

Uses

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

eczema

seborrheic dermatitis

psoriasis

insect bites

poison ivy, poison oak, and poison sumac

cosmetics

jewelry

detergents

soaps

temporarily relieves external anal and genital itching

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

Warnings

For external use only

When using this product

do not get into 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

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.

Stop us and ask 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

aloe barbadensis (aloe vera) leaf juice, cetearyl alcohol, glycerin, light mineral oil, potassium sorbate, purified water, sodium benzoate, sodium cetearyl sulfate, sodium lauryl sulfate, white petrolatum, white wax

Purpose

Anti-Itch

Content of labeling



Hydrocortisone Cream 1% with Aloe Vera

ANTI-ITCH PARABEN FREE

hydrocortisone cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:11383-313
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
HYDROCORTISONE (UNII: W4X0X7BP) (HYDROCORTISONE - UNII:W4X0X7BP)	HYDROCORTISONE	1 g in 100 g

Inactive Ingredients

Ingredient Name	Strength

PETROLATUM (UNII: 4T6H12BN9U)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	
GLYCERIN (UNII: PDC6A3C0OX)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
LIGHT MINERAL OIL (UNII: N6K5787QVP)	
POTASSIUM SORBATE (UNII: 1VPU26JZZ4)	
WATER (UNII: 059QF0KO0R)	
WHITE WAX (UNII: 7G1J5DA97F)	
SODIUM CETOSTEARYL SULFATE (UNII: 7ZBS06BH4B)	

Product Characteristics

Color	white	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:11383-313-01	1 in 1 CARTON	03/03/2023	
1		28 g in 1 TUBE; Type 0: Not a Combination Product		
2	NDC:11383-313-02	1 in 1 CARTON	03/03/2023	
2		56 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 Drug	M017	03/03/2023	

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

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

Establishment

Name	Address	ID/FEI	Business Operations
Weeks & Leo Co., Inc.		005290028	manufacture(11383-313)