

BARMICIL ANTI-ITCH- hydrocortisone cream
OPMX LLC

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.

Barmicil Hydrocortisone 2 oz

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, methylparaben, mineral oil, propylparaben, purified water, sodium cetearyl sulfate, sodium lauryl sulfate, white petrolatum, white wax

Purpose

Anti-Itch

Content of labeling



Aloe Vera

Hydrocortisone Cream 1% with

BARMICIL ANTI-ITCH

hydrocortisone cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:69729-301
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
HYDROCORTISONE (UNII: WI4X0X7BPJ) (HYDROCORTISONE - UNII:WI4X0X7BPJ)	HYDROCORTISONE	1 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
PETROLATUM (UNII: 4T6H12BN9U)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	
GLYCERIN (UNII: PDC6A3C0OX)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	

ALOE VERA LEAF (UNII: ZY81Z83H0X)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
LIGHT MINERAL OIL (UNII: N6K5787QVP)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
WATER (UNII: 059QF0K00R)	
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:69729-301-51	1 in 1 CARTON	02/10/2016	
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	02/10/2013	

Labeler - OPMX LLC (029918743)

Registrant - Weeks & Leo (005290028)

Establishment

Name	Address	ID/FEI	Business Operations
Weeks & Leo Co., Inc.		005290028	manufacture(69729-301)

Revised: 3/2016

OPMX LLC