

HYDROCORTISONE- hydrocortisone cream

Promex, 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.

Drug Facts

Active Ingredient

Hydrocortisone 1%

Purpose

Anti-itch

Uses

- temporarily relieves itching associated with minor skin irritation, 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

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 right away.

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: Ask a doctor
- for external anal and genital itching, adults:
- when practical, clean the affected area with mild soap and 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

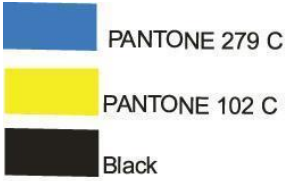
Other information

- store at 20 to 25 °C (68 to 77 °F)

Inactive Ingredient

Butylated hydroxytoluene, Cetyl alcohol, Glycerin, Glyceryl monostearate, Isopropyl myristate, Methylparaben, Propylparaben, Purified water, Squalane and Stearic acid

Hydrocortisone



Hydrocortisone 1% Cream 1oz_package

Cinahalar
Anti-Itch / Anti-Picazón

Cinahalar

Anti-Itch / Anti-Picazón

ProMex®

28.35 g. (1 oz.)

LOT & EXP.

Pro-Mex® Miami, FL 33179
 1 (305) 653-2700

Información del Medicamento

Propósito Hidrocortisone 1% Anti-picazón

Ingrediente activo (en cada gramo) Hidrocortisone 1% Anti-picazón

Usos ■ alivia temporalmente la comezón asociada con irritaciones menores de la piel, inflamaciones y erupciones debido a: eczemas ■ picaduras de insectos ■ hiedra venenosa, roble o zumaque ■ jabones ■ detergentes ■ cosméticos ■ dermatitis sebóricas ■ psoriasis ■ alivia temporalmente la comezón anal externa y/o comezón genital ■ otros usos de este producto deben ser solo bajo el asesoramiento y supervisión de un médico

Advertencias ■ No utilice en el área genital si tiene secreciones vaginales. Consulte a un médico para el tratamiento de la dermatitis del pañal.

Para uso externo solamente.

Al utilizar este producto ■ evite el contacto con los ojos ■ No exceda la dosis sugerida a menos que se lo recomiende un médico ■ No coloque directamente en el recto con los dedos o con cualquier dispositivo mecánico o aplicador

Suspenda el uso y pónguese a un doctor si ■ condición empeora, los síntomas persisten durante más de 7 días o desaparecen y vuelven a ocurrir en unos pocos días, y no comenzar el uso de cualquier otro producto con hidrocortisone a menos que lo haya recomendado un médico ■ sangrado rectal ocurre

Mantener fuera del alcance de los niños. En caso de ingestión, obtenga ayuda médica o contacte un Centro de Control de Intoxicación inmediatamente

Modo de empleo: ■ para la picazón de irritación de la piel, la inflamación y erupciones: para niños mayores de 2 años de edad y adultos, se aplican al área afectada no más de 3 a 4 veces al día ■ menores de 2 años: consulte a su médico ■ En adultos, para la comezón anal externa y/o comezón genital, cuando sea práctico, limpie el área afectada con agua y jabón y enjuague bien ■ seca suavemente con pañuelos o con papel higiénico o con un pañal suave antes de aplicar ■ aplicar al área afectada no más de 3 a 4 veces al día ■ Niños menores de 12 años de edad: Consulte a su médico

Drug Facts

Active Ingredient (in each gram) Hydrocortisone 1% Anti-itch

Purpose Anti-itch

Uses ■ temporarily relieves itching associated with minor skin irritations, inflammation, and rashes due to: eczemas ■ insect bites ■ poison ivy, oak, or sumac ■ soaps ■ detergents ■ cosmetics ■ jewelry ■ seborrheic dermatitis ■ psoriasis ■ dermatitis seborrheic ■ psoriasis ■ other uses of this product should only be under the advice and supervision of a doctor

Warnings ■ Do not use in the genital area if you have a vaginal discharge. Consult a doctor for the treatment of diaper rash.

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.

When using this product ■ avoid contact with eyes ■ do not use more than directed unless told to do so ■ 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.

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: Ask a doctor ■ for external anal and genital itching, adults: ■ when practical, clean the affected area with mild soap and water and rinse thoroughly ■ apply 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

Drug Facts (continued)

Other information ■ store at 20° to 25°C (68° to 77°F) ■ see end of carton or tube crimp for lot number and expiration date

Inactive ingredients butylated hydroxytoluene, cetyl alcohol, glycerin, glyceryl monostearate, isopropyl myristate, methylparaben, propylparaben, purified water, squaric acid, and stearic acid

Questions Comments? Pro-Mex® Miami, FL 33179 1 (305) 653-2700

Información del Medicamento (continuación)

Otros datos ■ almacene a 20° a 25° C (68° a 77° F) ■ vea la caja o tubo para encontrar el número de lote y fecha de vencimiento

Ingredientes inactivos hidroxitolueno butilado, alcohol cetílico, glicerina, monoestearato de glicerilo, metilparaben, propilparaben, agua purificada, escualeno, y ácido esteárico

HYDROCORTISONE

hydrocortisone cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:58988-0019
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
CETYL ALCOHOL (UNII: 936JST6JCN)	
BUTYLATED HYDROXYTOLUENE (UNII: 1P9D0Z171K)	
GLYCERIN (UNII: PDC6A3C0OX)	
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	
ISOPROPYL MYRISTATE (UNII: 0RE8K4LNJS)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
SQUALANE (UNII: GW89575KF9)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
WATER (UNII: 059QF0K00R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:58988-0019-1	1 in 1 BOX	11/15/2013	
1		28.35 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	11/15/2013	

Labeler - Promex, LLC (789974388)

Revised: 3/2018

Promex, LLC