

MAXIMUM STRENGTH HYDROCORTISONE - hydrocortisone ointment
DLC Laboratories, Inc

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.

Maximum Strength Hydrocortisone 1%

Active Ingredient

Hydrocortisone, USP 1%

Purpose

Antipruritic (Anti-Itch)

Uses

- for the temporary relief of itching associated with minor skin irritations, inflammation, and rashes due to eczema, insect bites, poison ivy, poison oak, poison sumac, soaps, detergents, cosmetics, jewelry, seborrheic dermatitis, psoriasis
- for external genital, feminine and anal itching
- other uses of this product should be only under the advice and supervision of a doctor

Warnings

For external use only.

Do not use

- for the treatment of diaper rash. Consult a doctor
- for external feminine itching if you have a vaginal discharge. Consult a doctor.

When using this product

- avoid contact with the eyes
- do not use more than directed unless told to do so by a doctor
- do not put this product into rectum by using fingers or any medical device or applicator

Stop use and ask a doctor

if

- condition worsens, or if symptoms persist for more than 7 days or clear up and occur again within a few days. Do not begin use of any other hydrocortisone product unless you have consulted a doctor
- rectal bleeding occurs

Keep out of the reach of children.

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

Directions

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: do not use. Consult a doctor

Other information

store at room temperature 15-30C (59-86F)

Inactive Ingredients

mineral oil, petrolatum

Product Labeling

For fast relief of itching due to:

- Eczema and Psoriasis
- Insect bites
- Soaps and detergents
- Poison Ivy and Poison Sumac

Maximum Strength Hydrocortisone 1%

For relief of itching, rashes, and skin irritations

Active Ingredient

Hydrocortisone, USP 1%.....Antipruritic (Anti-itch)

Purpose

Uses ■ for the temporary relief of itching associated with minor skin irritations, inflammation and rashes due to eczema, insect bites, poison ivy, poison oak, poison sumac, soaps, detergents, cosmetics, jewelry, seborrheic dermatitis, psoriasis ■ for external genital, feminine and anal itching ■ other uses of this product should be only under the advice and supervision of a doctor

Warnings For external use only. Do not use ■ for the treatment of diaper rash. Consult a doctor. ■ for external feminine itching if you have a vaginal discharge. Consult a doctor. **When using this product** ■ avoid contact with the eyes ■ do not use more than directed unless told to do so by a doctor ■ do not put this product into rectum by using fingers or any mechanical device or applicator. **Stop use and ask a doctor if** ■ condition worsens, or if symptoms persist for more than 7 days or clear up and occur again within a few days. Do not begin use of any other hydrocortisone product unless you have consulted a doctor. ■ rectal bleeding occurs

KEEP OUT OF THE REACH OF CHILDREN. If swallowed, get medical help or contact a Poison Control Center right away.

Directions 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:** do not use. Consult a doctor. **Adults: for external anal itching:** ■ 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 application of this product. **Children under 12 years of age:** for external anal itching, consult a doctor.

Other information ■ store at room temperature 15°-30°C (59°-86°F)

Inactive ingredients mineral oil, petrolatum

Distributed by:

De La Cruz Products, A Division of DLC Laboratories, Inc.,
Paramount, CA 90723 USA

Questions: 1-800-858-3889 dlclabs.com © DLC

P0191-AZX



Maximum Strength

Ointment

Hydrocortisone 1%

For Relief of Itching, Rashes and Skin Irritations

Net Wt. 1 OZ (28g)

Fragrance Free • Rapid Relief



- **Fragrance Free**
- **Rapid Relief**

Maximum Strength Hydrocortisone 1%

**For Relief of Itching, Rashes
and Skin Irritations**

Ointment

- For fast relief of itching due to:**
- **Eczema and Psoriasis**
 - **Insect Bites**
 - **Soaps and Detergents**
 - **Poison Ivy and Poison Sumac**

- Para el alivio rápido de comezón debido a:**
- **Ecceema y soriasis**
 - **Picaduras de insectos**
 - **Uso de jabones y detergentes**
 - **Hiedra venenosa y zumaque venenoso**

3-24286-17011-1



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A Division of DLC Laboratories, Inc.
Paramount, CA 90723 USA
Questions / Preguntas: 1-800-858-3889

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FORM 82X

<p>Ingredientes inactivos aceite mineral, petrolato</p> <p>Otra información ■ guarde a temperatura ambiente 15°-30°C (59°-86°F) con un médico</p> <p>Miños menores de 12 años de edad: para comedón anal externa, consulte usando papel de baño o un pedo suave antes de aplicar este producto. ■ cuando sea práctico, limpie el área afectada con un jabón suave y agua tibia y enjuague completamente. ■ seque cuidadosamente con toquitos.</p> <p>Adultos; para comedón anal externa:</p> <p>Para niños menores de 2 años: no lo use. Consulte con su médico. ■ más de 3 a 4 veces al día.</p> <p>Para adultos y niños mayores de 2 años: aplique al área afectada no más de 3 a 4 veces al día.</p> <p>Instrucciones</p> <p>Evite el contacto con los ojos. ■ no exceda la dosis recomendada. ■ evite el contacto con las manos que así lo indique un médico. ■ no ponga este producto dentro del recto usando los dedos o cualquier dispositivo médico o aplicador. ■ obtenga asistencia médica o contáctese con un Centro de Control de Envenenamientos inmediatamente.</p> <p>MANTÉNGASE FUERA DEL ALCANCE DE LOS NIÑOS. En caso de ingestión, menos que haya consultado con un médico. ■ tiene sangrado rectal a los pocos días. No inicie el uso de otro producto con hidrocortisona a si persisten los síntomas más de 7 días o si desaparecen y reaparecen. ■ deje de usar y consulte con un médico si ■ la reacción empeora o si persisten los síntomas más de 7 días o si desaparecen y reaparecen.</p> <p>Deje de usar y consulte con un médico si: ■ la condición empeora o si persisten los síntomas más de 7 días o si desaparecen y reaparecen. ■ el centro del recto usando los dedos o cualquier dispositivo médico o aplicador. ■ obtenga asistencia médica o contáctese con un Centro de Control de Envenenamientos inmediatamente.</p> <p>Para uso externo únicamente</p> <p>Advertencias</p> <p>No lo use ■ para el tratamiento del sarpullido por pañales. Consulte con un médico. ■ en casos de comedón externa terminala si Ud. tiene flujo vaginal.</p> <p>Consulte con un médico.</p> <p>■ evite el contacto con los ojos. ■ no exceda la dosis recomendada. ■ evite el contacto con las manos que así lo indique un médico. ■ no ponga este producto dentro del recto usando los dedos o cualquier dispositivo médico o aplicador. ■ obtenga asistencia médica o contáctese con un Centro de Control de Envenenamientos inmediatamente.</p> <p>MANTÉNGASE FUERA DEL ALCANCE DE LOS NIÑOS. En caso de ingestión, menos que haya consultado con un médico. ■ tiene sangrado rectal a los pocos días. 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Consulte con un médico. ■ en casos de comedón externa terminala si Ud. tiene flujo vaginal.</p> <p>Consulte con un médico.</p> <p>■ evite el contacto con los ojos. ■ no exceda la dosis recomendada. ■ evite el contacto con las manos que así lo indique un médico. ■ no ponga este producto dentro del recto usando los dedos o cualquier dispositivo médico o aplicador. ■ obtenga asistencia médica o contáctese con un Centro de Control de Envenenamientos inmediatamente.</p>	<p>Other information ■ store at room temperature 15°-30°C (59°-86°F)</p> <p>Children under 12 years of age: for external anal itching, consult a doctor. ■ 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 application of this product.</p> <p>Adults; for external anal itching:</p> <p>Children under 2 years of age: do not use. Consult a doctor. ■ more than 3 to 4 times daily.</p> <p>Adults and children 2 years of age and older: apply to affected area not more than 3 to 4 times daily.</p> <p>Directions</p> <p>KEEP OUT OF THE REACH OF CHILDREN. If swallowed, get medical help or contact a Poison Control Center right away.</p> <p>■ rectal bleeding occurs</p> <p>■ condition worsens, or if symptoms persist for more than 7 days or clear up and occur again within a few days. Do not begin use of any other hydrocortisone product unless you have consulted a doctor.</p> <p>Stop use and ask a doctor if: ■ condition worsens, or if symptoms persist for more than 7 days or clear up and occur again within a few days. Do not begin use of any other hydrocortisone product unless you have consulted a doctor.</p> <p>When using this product ■ avoid contact with the eyes. ■ do not use more than directed unless told to do so by a doctor. ■ do not put this product into return by using fingers or any mechanical device or applicator.</p> <p>Do not use ■ for the treatment of diaper rash. Consult a doctor. ■ for external female itching if you have a vaginal discharge. Consult a doctor.</p> <p>Warnings</p> <p>For external use only</p> <p>Do not use ■ for the treatment of diaper rash. Consult a doctor. ■ for external female itching if you have a vaginal discharge. Consult a doctor.</p> <p>■ other uses of this product should be only under the advice and supervision of a doctor.</p> <p>poison oak, poison sumac, soaps, detergents, cosmetics, jewelry, seborrhoeic dermatitis, psoriasis ■ for external genital, female and anal itching</p>
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Uses ■ for the temporary relief of itching associated with minor skin irritations, inflammation, and rashes due to eczema, insect bites, poison ivy, inflammaciones y sarquillos leves de la piel debido a eccemas, picaduras.	Usos ■ para el alivio temporal de la comezón asociada con irritaciones, inflamaciones y sarquillos leves de la piel debido a eccemas, picaduras.
Active ingredient Hydrocortisone, USP 1% Antipruritic (Anti-Itch)	Ingrediente activo Hidrocortisona, USP 1% Antipruriginoso (contra la comezón)
Drug Facts	Datos Medicinales

MAXIMUM STRENGTH HYDROCORTISONE

hydrocortisone ointment

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:24286-1560
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
HYDROCORTISONE (UNII: WI4X0 X7BPJ) (HYDROCORTISONE - UNII:WI4X0 X7BPJ)	HYDROCORTISONE	1 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
MINERAL OIL (UNII: T5L8T28 FGP)	
PETROLATUM (UNII: 4T6 H12BN9 U)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:24286-1560-1	1 in 1 BOX		
1		28 g in 1 TUBE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	03/22/2013	

Labeler - DLC Laboratories, Inc (093351930)

Revised: 3/2013

DLC Laboratories, Inc