

VITACILINA ANTI ITCH HYDROCORTISONE- hydrocortisone cream
Taisho Pharmaceutical California Inc.

Vitacilina Anti Itch Hydrocortisone

Drug Facts

Active ingredient (in each gram)

Hydrocortisone 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
- and for external anal and genital itching.

Warnings

For external use only.

Avoid contact with eyes

Do not use

- if you have a vaginal discharge. Consult a doctor.

When using this product

- do not exceed the recommended daily dosage unless directed 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 worsens
- bleeding occurs
- symptoms persist for more than 7 days or clear up and occurs again within a few days.

If pregnant or breast-feeding,

ask a health professional before use.

Keep out of reach of children.

If swallowed, get medical help or contact a Poison Control Center (1-800-222-1222)

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 of age:consult a doctor

For external anal and genital itching:

Adults and children 12 years of age and older:

- when practical, cleanse the affected area with mild soap or warm water and rinse thoroughly by patting or blotting with an appropriate cleansing pad
- gently dry by patting or blotting with toilet tissue or a soft cloth before application of this product
- apply to affected area not more than 3 to 4 times daily
- **children under 12 years of age:**consult a doctor

Other information

- store at 15 to 30°C (59 to 86°F)
- **Tamper Evident:**DO NOT USE IF SEAL ON TUBE IS BROKEN OR MISSING.

Inactive ingredients

- aloe barbadensis leaf juice, carbomer, cetyl alcohol, DMDM hydantoin, glyceryl stearate, isopropyl alcohol, methylparaben, mineral oil, polysorbate-20, propylparaben, purified water, stearic acid, triethanolamine, trisodium EDTA

Package Labeling:

Drug Facts (continued)

Children under 2 years of age: consult a doctor
For external anal and genital itching:
Adults and children 12 years of age and older: • when practical, cleanse the affected area with mild soap or 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 application of this product
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PL33105B
V01

DISTRIBUTED BY TaiSho Pharmaceutical California Inc. 3528 Torrance Blvd., Suite #320 Torrance, CA 90503 U.S.A.

NDC 81929-005-01

ANTI-ITCH • HYDROCORTISONE

VITACILINA®

- Eczema • Psoriasis • Seborrheic Dermatitis
- Soaps • Insect Bites • Poison Ivy, Oak & Sumac

NET WT 1 OZ (28 g)



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HYDROCORTISONE

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Active ingredient (in each gram)
Hydrocortisone 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 • and for external anal and genital itching.

Warnings

For external use only.
Avoid contact with eyes
Do not use • if you have a vaginal discharge. Consult a doctor.

Drug Facts (continued)

When using this product • do not exceed the recommended daily dosage unless directed 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 worsens • bleeding occurs • symptoms persist for more than 7 days or clear up and occurs again within a few days.

If pregnant or breast-feeding, ask a health professional before use.

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center (1-800-222-1222) 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

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- Eczema • Psoriasis • Seborrheic Dermatitis • Soaps
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<p>Active ingredient Hydrocortisone 1%.....Antipruritic (anti-itch)</p> <p>Purpose</p> <p>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 ■ and for external anal and genital itching.</p> <p>Warnings For external use only.</p> <p>Avoid contact with eyes.</p> <p>Do not use ■ if you have a vaginal discharge. Consult a doctor.</p> <p>When using this product ■ do not exceed the recommended daily dosage unless directed by a doctor ■ do not put into the rectum by using fingers or any mechanical device or applicator</p> <p>Stop use and ask a doctor if ■ condition worsens ■ symptoms persist for more than 7 days or clear up and occurs again within a few days ■ bleeding occurs</p> <p>If pregnant or breast-feeding, ask a health professional before use.</p> <p>Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away: 800-222-1222. ▶</p>	<p>Directions For itching associated with minor skin irritations, 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 of age: Consult a doctor For external anal and genital itching: Adults and children 12 years of age and older: ■ when practical, cleanse the affected area with mild soap or 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 application of this product ■ apply to affected area not more than 3 to 4 times daily Children under 12 years of age: Consult a doctor</p> <p>Other information Store at 15 to 30°C (59 to 86°F). Tamper Evident: DO NOT USE IF SEAL ON TUBE IS BROKEN OR MISSING.</p> <p>Inactive ingredients aloe barbadensis leaf juice, carbomer, cetyl alcohol, DMDM hydantoin, glyceryl stearate, isopropyl alcohol, methylparaben, mineral oil, polysorbate-20, propylparaben, purified water, stearic acid, triethanolamine, trisodium EDTA</p> <p><small>DISTRIBUTED BY Taisho Pharmaceutical California Inc. 3528 Torrance Blvd, Suite #320 Torrance, CA 90503 U.S.A.</small></p>
	<p>PL33105T V01</p>

VITACILINA ANTI ITCH HYDROCORTISONE

hydrocortisone cream

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:81929-005
Route of Administration	TOPICAL		
Active Ingredient/Active Moiety			
	Ingredient Name	Basis of Strength	Strength
	HYDROCORTISONE (UNII: W4X0X7BPJ) (HYDROCORTISONE - UNII:W4X0X7BPJ)	HYDROCORTISONE	10 mg in 1 g
Inactive Ingredients			
	Ingredient Name	Strength	
	ALOE VERA LEAF (UNII: ZY81Z83H0X)		

CARBOMER HOMOPOLYMER, UNSPECIFIED TYPE (UNII: 0A5MM307FC)
CETYL ALCOHOL (UNII: 936JST6JCN)
DMDM HYDANTOIN (UNII: BYR0546TOW)
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)
ISOPROPYL ALCOHOL (UNII: ND2M416302)
METHYLPARABEN (UNII: A2I8C7HI9T)
MINERAL OIL (UNII: T5L8T28FGP)
POLYSORBATE 20 (UNII: 7T1F30V5YH)
PROPYLPARABEN (UNII: Z8IX2SC1OH)
WATER (UNII: 059QF0KO0R)
STEARIC ACID (UNII: 4ELV7Z65AP)
TROLAMINE (UNII: 9O3K93S3TK)
EDETATE TRISODIUM (UNII: 420IP921MB)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:81929-005-01	1 in 1 CARTON	10/01/2024	
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 Drug	M017	10/01/2024	

Labeler - Taisho Pharmaceutical California Inc. (603827635)

Revised: 8/2024

Taisho Pharmaceutical California Inc.