

HYDROCORTISONE CREAM 1%- hydrocortisone cream 1% cream SOLA Pharmaceuticals

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.

Hydrocortisone Cream 1%

Active Ingredient

Hydrocortisone 1%

Purpose

Antipruritic (Anti-itch)

Uses

Relieves itches and rashes due to:

- Eczema
- Psoriasis
- Seborrheic dermatitis
- Poison ivy
- Poison oak
- Poison sumac
- Insect bites
- External anal itching
- Soaps
- Detergents
- Cosmetics
- Jewelry

Temporary relief of external anal and genital itching.

Other use of the product should only be under the advice and supervision of a doctor.

Warnings

For external use only

Do not use:

- In the eyes
- For diaper rash
- If you have vaginal discharge
- More than the recommended dosage

Ask doctor before use:

- If you are pregnant or breast feeding

Stop use and ask a doctor if:

- Condition worsens, or is 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.

When using this product:

- Do not put this product into rectum by using fingers or any mechanical device or applicator.

Keep out of reach of children. If swallowed, get medical help or contact Poison Control Center right away

Directions

- **Adults and children over 2 years of age** - Apply to affected area not more than 3-4 times per day.
- **Children under 2 years of age** - Do not use. Consult a doctor.
 - **For external anal itching Adults** - When practical cleanse the affected area with mild soap and water and rinse thoroughly. Gently dry patting with bathroom tissue or soft cloth before applying. Apply to affected area not more than 3-4 times per day. Children under 12 years of age: consult a doctor.

Other Information

- store between 20°C and 25°C (68°F and 77°F)
- avoid excessive heat and humidity

Inactive Ingredients

Cetomacrogol 1000, Cetostearyl alcohol, Chlorocresol, Disodium EDTA, Liquid paraffin, Propylene glycol, Purified water, Sodium metabisulphite, White soft paraffin.

Questions or comments? Call 1-866-747-7365

Manufactured for : SOLA Pharmaceuticals

Baton Rouge, LA 70810

Store in a dry, cool place

Hydrocortisone 1% Cream

NDC 70512-101-30

Qty: 28.4g

NDC 70512-0101-30

Anti-Itch
Cream

Hydrocortisone

CREAM USP, 1%

MAXIMUM STRENGTH CREAM

Relieves itches and rashes due to: Eczema, psoriasis, seborrheic dermatitis, poison ivy, poison oak, poison sumac, insect bites, external anal itching, soaps, detergents, cosmetics, and jewelry.

Hydrocortisone
CREAM USP, 1%



Hydrocortisone

CREAM USP, 1%

Anti-itch Cream

NET WT. 1 OZ. (28.4 G)

Hydrocortisone
CREAM USP, 1%



This product is not affiliated with, manufactured by, or produced by the makers of owners of, Contair® or Cortisone-10®. SOLA PHARMACEUTICALS, Baton Rouge, LA 70810

Drug Facts (Continued)
Other Information ■ Store between 20°C and 25°C (68°F and 77°F) ■ avoid excessive heat and humidity.
Inactive Ingredients: Calcium alginate, Carbomer, Chlorhexidine, Disodium EDTA, Liquid Paraffin, Propylene Glycol, Purified Water, Sodium metabisulfite, White Soft Paraffin.
Questions or comments? Call 1-866-747-7385.

Drug Facts
Active Ingredient Hydrocortisone Acetate USP 1% w/w Antipruritic (Anti-Itch)
Purpose Relieves itches and rashes due to: Eczema, psoriasis, seborrheic dermatitis, poison ivy, poison oak, poison sumac, insect bites, external anal itching, soaps, detergents, cosmetics, and jewelry. Temporary relief of external anal and genital itching. Other use of the product should only be under the advice and supervision of a doctor.
Warnings:
For external use only ■ Do not use in the eyes ■ If you have vaginal discharge ■ more than the recommended dosage
Ask a doctor before use ■ If you are pregnant or breast-feeding
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 week.
Directions:
■ Adult and children over 2 years of age - Apply to affected area not more than 3-4 times per day.
■ Children under 2 years of age - Do not use. Consult a doctor.
■ For external anal itching Adults - When practical cleanse the affected area with mild soap and water and rinse thoroughly. Gently dry patting with bathroom tissue or soft cloth before applying.
■ Apply to affected area not more than 3-4 times per day.
■ Children under 12 years of age: consult a doctor.
When using this product ■ do not put this product into rectum by using fingers or any mechanical device or applicator
Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

Hydrocortisone

CREAM USP, 1%



Relieves Itching
& Burning

NDC 70512-0101-30

MAXIMUM STRENGTH



Hydrocortisone

CREAM USP, 1%

Anti-itch Cream

NET WT. 1 OZ. (28.4 G)

8X3mm

1mm

SR

Drug Facts

Active ingredient

Hydrocortisone Acetate USP 1% w/w

Purpose

Antipruritic (Anti-itch)

Uses: Relieves itches and rashes due to: Eczema, psoriasis, seborrheic dermatitis, poison ivy, poison oak, poison sumac, insect bites, external anal itching, soaps, detergents, cosmetics, and jewelry. Temporary relief of external anal and genital itching. Other use of the product should only be under the advice and supervision of a doctor. **Warnings:** For external use only Do not use in the eyes for diaper rash if you have vaginal discharge more than the recommended dosage Ask a doctor before use if you are pregnant or breast feeding 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, and do not begin use of any other hydrocortisone product unless you have asked a doctor When using this product do not put this product into rectum by using fingers or any mechanical device or applicator Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away **Directions:** Adult and children over 2 years of age – apply to affected area not more than 3-4 times per day. Children under 2 years of age – Do not use. Consult a doctor. For external anal itching Adults - When practical cleanse the affected area with mild soap and water and rinse thoroughly. Gently dry patting with bathroom tissue or soft cloth before applying. Apply to affected area not more than 3-4 times per day Children under 12 years of age: consult a doctor **Other information** store between 20°C and 25°C (68°F and 77°F) avoid excessive heat and humidity. **Inactive ingredients:** Cetomacrogol 1000, Cetostearyl alcohol, Chlorocresol, Disodium EDTA, Liquid Paraffin, Propylene Glycol, Purified water, Sodium metabisulphite, White soft paraffin. **Questions?** Call 1-866-747-7365.

Manufactured for: SOLA Pharmaceuticals, Baton Rouge, LA 70810

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HYDROCORTISONE CREAM 1%

hydrocortisone cream 1% cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:70512-101
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
WATER (UNII: 059QF0KO0R)	
PETROLATUM (UNII: 4T6H12BN9U)	
CETETH-20 (UNII: I835H2IHHX)	
DISODIUM EDTA-COPPER (UNII: 6V475AX06U)	
CHLOROCRESOL (UNII: 36W53O7109)	
MINERAL OIL (UNII: T5L8T28FGP)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SODIUM METABISULFITE (UNII: 4VON5FNS3C)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70512-101-30	1 in 1 CARTON	04/16/2020	
1		30 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	04/16/2020	

Labeler - SOLA Pharmaceuticals (080121345)

Revised: 7/2022

SOLA Pharmaceuticals