

HYDROCORTISONE- antipruritic (anti-itch) cream
BluePoint Laboratories

Hydrocortisone 1% Cream

Drug Facts

Active Ingredient

Hydrocortisone USP 1%

Purpose

Antipruritic (Anti-Itch)

Uses

For 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, and for external genital, feminine, and anal itching.

Warnings

For external use only

If pregnant or breast-feeding,

ask a health professional before use

Do not use

- in the eyes
- for diaper rash
- for external genital or feminine itching if you have a vaginal discharge
- more than the recommended daily dosage unless directed by a doctor
- this product in the rectum by using fingers or any mechanical device or applicator

Ask a doctor before use if you are using any other hydrocortisone product

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 continue to use this or any other hydrocortisone product
- in case of bleeding when used for anal itching

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 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.
- When used for anal itching, cleanse the affected area with mild soap and warm water and rinse thoroughly. Gently dry, patting or blotting with bathroom tissue or soft cloth before applying.
- Children under 12: consult a doctor before using for anal itching.

Other Information

- Do not use if seal on the tube is damaged or is not visible. To open, unscrew cap, pull tab to remove foil seal
- Store at room temperature
- Avoid excessive heat
- Preserve in well-closed container
- See crimp of tube or carton for Lot Number and Expiry Date

Inactive Ingredients

Cetostearyl Alcohol, Glyceryl Monostearate SE, Methylchloroisothiazolinone, Propylene Glycol, Purified Water, Stearic Acid, Trolamine, White Petrolatum

Questions?

Contact 1-800-707-4621

Manufactured in India by:

Gopaldas Visram & Company Limited

Plot No. A327, T.T.C Indl. Area, M.L.D.C

Mahape, Navi Mumbai - 400710.

Mfg. Lic. No.: KD/503

For BluePoint Laboratories

Rev 10/2021

Label

Hydrocortisone Cream, USP 1%

136.18mm

(Tube length upto shoulder - 129mm ± 2.0mm)

(Tube Dia - 22mm ± 0.5mm)
73mm

NDC: 88001-476-46

Hydrocortisone Cream, USP 1%

Anti-Itch Cream

Net Wt. 1.05 oz (30 g)

Manufactured in India by:
Gopikaa Varma & Company Limited,
Plot No. A327, E.T.C. Ind. Area, M.I.D.C.,
Madhapur, Navi Mumbai - 400710.
Mfg. Lic. No.: KD/503
For BluePoint Laboratories

| Drug Facts | Drug Facts (continued) |
|--|---|
| Active Ingredient Hydrocortisone USP 1% | Purpose Antipruritic (Anti-itch) |
| Uses For temporary relief of itching associated with minor skin irritations, inflammation, and rashes due to eczema, insect bites, poison ivy, poison oak, poison sumac, sunburn, dermatitis, contact, sunburn, allergic dermatitis, psoriasis and for external genital, hemorrhoid, and anal itching. | Warnings Do not use in the eye or for diaper rash or for external genital or hemorrhoid itching if you have a vaginal discharge or more than the recommended daily dosage unless directed by a doctor in the product in the red box by using figure or any mechanical device or applicator. Ask a doctor before use if you are using any other hydrocortisone product. |
| Warnings For external use only. If pregnant or breast-feeding, ask a health professional before use. | Other Information Do not use if seal on the tube is damaged or is not visible. To open, unscrew cap, pull tab to remove foil seal. Store at room temperature or avoid excessive heat. Preserve in well-closed container in the event of rain or dust. For Lot Number and Expiry Date. |
| Do not use in the eye or for diaper rash or for external genital or hemorrhoid itching if you have a vaginal discharge or more than the recommended daily dosage unless directed by a doctor in the product in the red box by using figure or any mechanical device or applicator. | Questions? Contact 1-800-707-4521 |
| Ask a doctor before use if you are using any other hydrocortisone product. | Important: See box for complete Drug Facts |

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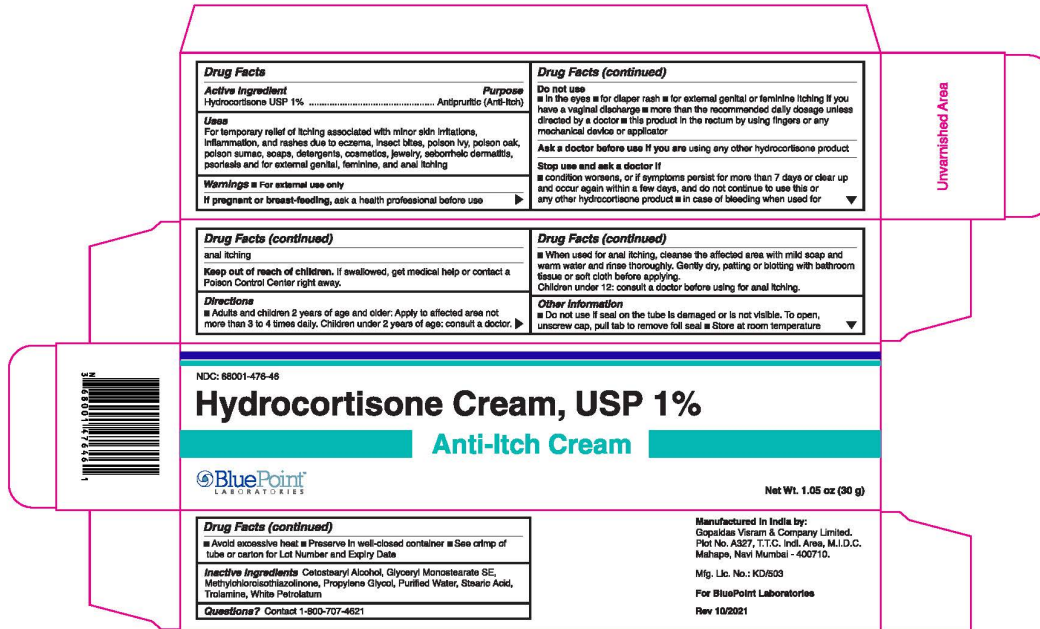
Rev 10/2021

- 100% PANTONE 293 C
- 100% PANTONE 549 C
- 75% Black

- 100% PANTONE Blue 072 C
- 100% PANTONE 2398 C
- 100% Black

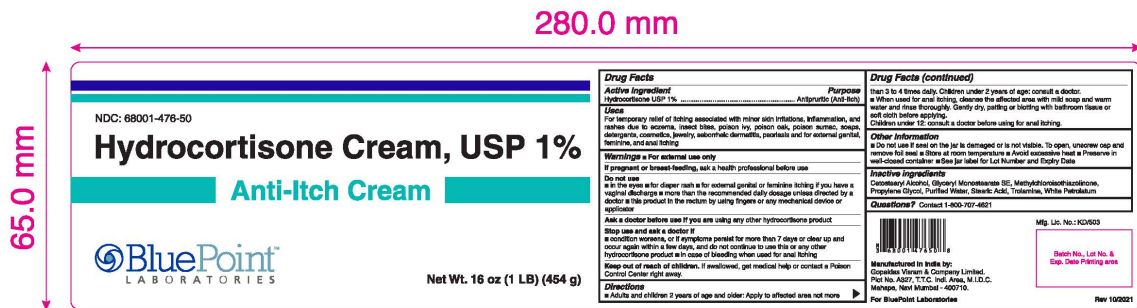
Hydrocortisone Cream, USP 1%

Size : L 147.0 x w26.0 x h35.0



- 100% PANTONE 293 C
- 100% PANTONE Blue 072 C
- 100% PANTONE 549 C
- 100% PANTONE 2398 C
- 75% Black
- 100% Black

Hydrocortisone Cream, USP 1% Jar



- 100% PANTONE 293 C
- 100% PANTONE Blue 072 C
- 100% PANTONE 549 C
- 100% PANTONE 2398 C
- 75% Black
- 100% Black

HYDROCORTISONE

antipruritic (anti-itch) cream

Product Information

| | | | |
|--------------------------------|----------------|---------------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:68001-476 |
| Route of Administration | TOPICAL | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|--|--------------------------|-----------------|
| HYDROCORTISONE (UNII: W4X0X7BPJ) (HYDROCORTISONE - UNII:W4X0X7BPJ) | HYDROCORTISONE | 1 g in 100 g |

Inactive Ingredients

| Ingredient Name | Strength |
|--|-----------------|
| WHITE PETROLATUM (UNII: B6E5W8RQJ4) | |
| STEARIC ACID (UNII: 4ELV7Z65AP) | |
| TROLAMINE (UNII: 9O3K93S3TK) | |
| PROPYLENE GLYCOL (UNII: 6DC9Q167V3) | |
| WATER (UNII: 059QF0KO0R) | |
| CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S) | |
| GLYCERYL STEARATE SE (UNII: FCZ5MH785I) | |
| METHYLCHLOROISOTHIAZOLINONE (UNII: DEL7T5QRPN) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|---|----------------------|--------------------|
| 1 | NDC:68001-476-46 | 1 in 1 CARTON | 11/27/2020 | |
| 1 | | 30 g in 1 TUBE; Type 0: Not a Combination Product | | |
| 2 | NDC:68001-476-50 | 454 g in 1 JAR; Type 0: Not a Combination Product | 11/27/2020 | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|---------------------------|---|-----------------------------|---------------------------|
| OTC Monograph Drug | M017 | 11/27/2020 | |

Labeler - BluePoint Laboratories (985523874)

Establishment

| Name | Address | ID/FEI | Business Operations |
|----------------------------|----------------|---------------|----------------------------|
| Gopaldas Visram & Co., Ltd | | 858030888 | manufacture(68001-476) |

