

## **HYDROCORTISONE- antipruritic (anti-itch) ointment**

### **BluePoint Laboratories**

*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.*

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## **Hydrocortisone Ointment, USP 1%**

### **Drug Facts**

#### ***Active ingredient***

Hydrocortisone Acetate 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. Do not continue to use this or any other hydrocortisone product for longer than 7 days, or if bleeding occurs near anus 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**

Mineral Oil, Sorbitan Sesquioleate, 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.I.D.C

Mahape, Navi Mumbai - 400710.

Mfg. Lic. No.: KD/503

### **For BluePoint Laboratories**

Rev 01/2022

### **Label**

Hydrocortisone Ointment, USP 1%

136.18mm

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

(Tube Dia - 22mm ± 0.5mm)  
73mm

NDC: 68001-526-45

# Hydrocortisone Ointment, USP 1%

## Anti-Itch Ointment

**BluePoint**  
LABORATORIES

Net Wt. 1 oz (28.4 g)

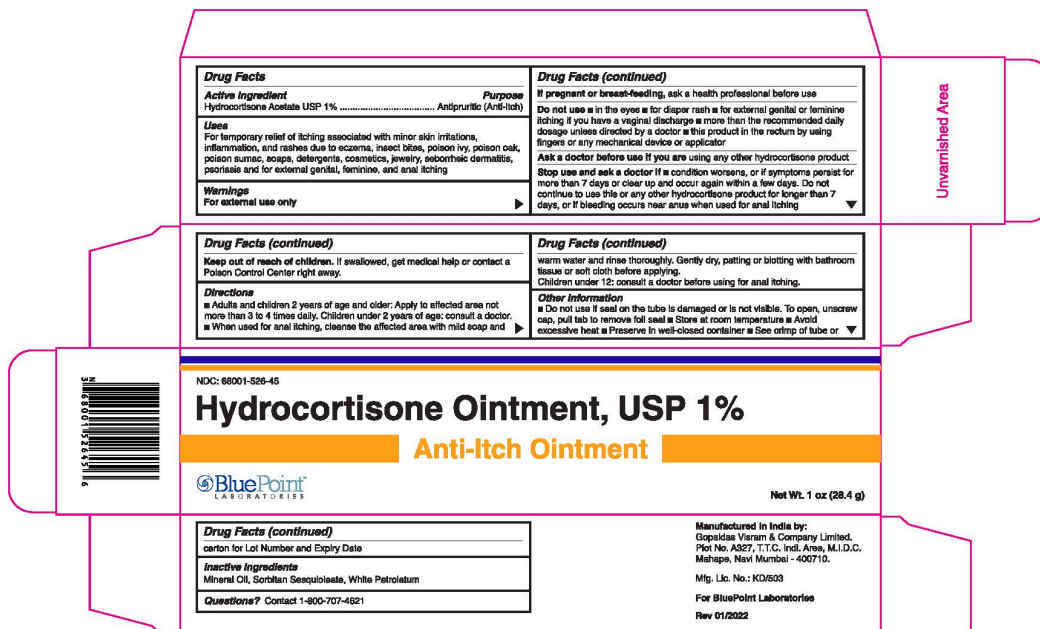
<p><b>Drug Facts</b></p> <p><b>Active ingredient:</b> Hydrocortisone Acetate USP 1% ..... Antipruritic (Anti-Itch)</p> <p><b>Warnings:</b> For temporary relief of itching associated with minor skin irritations, inflammation, and rashes due to eczema, insect bites, poison ivy, poison oak, poison sumac, scabs, dermatitis, contact, jewelry, cosmetic dermatitis, psoriasis and for external genital, feminine, and anal itching.</p> <p><b>Directions:</b> For external use only. If pregnant or breast-feeding, ask a health professional before use.</p> <p>Do not use as in the eyes or for diaper rash or for external genital or feminine itching. If you have a vaginal discharge or more than the recommended daily coverage unless directed by a doctor in this product in the rectum by using fingers or any mechanical device or applicator.</p>	<p><b>Drug Facts (continued)</b></p> <p><b>Ask a doctor before use if you are using any other hydrocortisone product.</b></p> <p><b>Stop use and ask a doctor if a condition worsens, or if symptoms persist for more than 7 days or clear up and occur again within a few days. Do not continue to use this or any other hydrocortisone product for longer than 7 days, or if bleeding occurs near anus when used for anal itching.</b></p> <p><b>Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.</b></p> <p><b>Other information:</b> Do not use if seal on the Tube is damaged or is not visible. To open, unscrew cap, pull tab to remove foil seal as shown at room temperature. Avoid excessive heat. Preserve in well-closed container in the strip of tube or carton for Lot Number and Expiry Date.</p> <p><b>Questions? Contact 1-800-797-4621</b></p> <p><b>Important! See box for complete Drug Facts</b></p>	<p>Manufactured in India by: Gepolasa Varam &amp; Company Limited, Plot No. 4062, T.T.C. Ind. Area, M.J.D.C. Mahaip, Near Mumbai - 400710.</p> <p>Mfg. Lk. No.: KD0603 For BluePoint Laboratories</p>  <p>3 168001 152645 6</p> <p>Rev 01/2022</p>
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- 100% PANTONE 293 C
- 100% PANTONE 549 C
- 75% Black

- 100% PANTONE Blue 072 C
- 100% PANTONE 1375 C
- 100% Black

10.01.2022

Size: (L)147.0mm x (W)26.0mm x (H)35.0mm



10.01.2022

## Hydrocortisone Ointment, USP 1%

### HYDROCORTISONE

antipruritic (anti-itch) ointment

#### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:68001-526
<b>Route of Administration</b>	TOPICAL		

#### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>HYDROCORTISONE ACETATE</b> (UNII: 3X7931PO74) (HYDROCORTISONE - UNII:W4X0X7BPJ)	HYDROCORTISONE ACETATE	1 g in 100 g

#### Inactive Ingredients

Ingredient Name	Strength
<b>WHITE PETROLATUM</b> (UNII: B6E5W8RQJ4)	
<b>SORBITAN SESQUIOLEATE</b> (UNII: 0W8RRI5W5A)	
<b>MINERAL OIL</b> (UNII: T5L8T28FGP)	

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:68001-526-45	1 in 1 CARTON	05/17/2023	
1		28.4 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	05/17/2023	

**Labeler** - BluePoint Laboratories (985523874)

## Establishment

Name	Address	ID/FEI	Business Operations
Gopaldas Visram & Co., Ltd		858030888	manufacture(68001-526)

Revised: 5/2023

BluePoint Laboratories