

## **HYDROCORTISONE- hydrocortisone cream**

**B8 Sales, 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.*

-----

### **PIO Put it on®**

#### **1% Hydrocortisone Cream™**

For Temporary Relief of Itching Associated with Minor Skin Irritations, Inflammation or Rashes

25 Packets

Each Packet Net.Wt.0.9gm

### **Drug Facts**

#### **Active ingredient**

Hydrocortisone 1.0%

#### **Purpose**

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 and scrapes
- 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
- not for external genital, feminine and anal itching

#### **Ask a doctor before use:**

- for external itching, do not exceed the recommended daily dosage, or if bleeding occurs
- if condition worsens or if symptoms persist for more than 7 days or clear up and occur again within a few days

#### **When using this product**

- avoid contact with eyes
- do not put this product into rectum or vagina by using fingers or any mechanical device or applicator

#### **Do not use**

- with any other Hydrocortisone product unless you have consulted a doctor • for feminine itching

#### **KEEP OUT OF REACH OF CHILDREN.**

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

**Directions**

- for adults and children 2 years of age and older apply to affected area 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 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

**Other information**

- store at room temperature (do not freeze)
- do not use any opened or torn packets

**Inactive ingredients**

emulsifying wax, ethanol, methylparaben, mineral oil, paraffin, petrolatum, propylparaben, purified water, white wax

Manufactured for: **B8 SALES**

Cincinnati, Ohio 45215

**Principal Display Panel**

1% Hydrocortisone Cream – Carton Label

PIO Put it on®

1% **Hydrocortisone Cream™**

**For Temporary Relief of Itching Associated with Minor Skin Irritations, Inflammation or Rashes**

**25 Packets**

**Each Packet Net.Wt.0.9gm**



## HYDROCORTISONE

hydrocortisone cream

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:50607-5802
<b>Route of Administration</b>	TOPICAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
hydrocortisone (UNII: WI4X0X7BPJ) (hydrocortisone - UNII:WI4X0X7BPJ)	hydrocortisone	10 mg in 1g

### Inactive Ingredients

Ingredient Name	Strength
Ethanol (UNII: 3K9958V90M)	
methylparaben (UNII: A2I8C7HI9T)	
mineral oil (UNII: T5L8T28FGP)	
paraffin (UNII: I9O0E3H2ZE)	
petrolatum (UNII: 4T6H12BN9U)	
propylparaben (UNII: Z8IX2SC1OH)	
water (UNII: 059QF0K00R)	
white wax (UNII: 7G1J5DA97F)	

**Product Characteristics**

<b>Color</b>	white (white)	<b>Score</b>	
<b>Shape</b>		<b>Size</b>	
<b>Flavor</b>		<b>Imprint Code</b>	
<b>Contains</b>			

**Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:50607-5802-1	25 in 1 BOX		
1		.9 g in 1 POUCH		
2	NDC:50607-5802-2	144 in 1 BOX		
2		.9 g in 1 POUCH		

**Marketing Information**

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part347	05/01/2010	

**Labeler** - B8 Sales, Inc. (833208635)

Revised: 4/2010

B8 Sales, Inc.