

**HYDROCORTISONE- hydrocortisone cream**  
**Padagis Israel Pharmaceuticals Ltd**

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**Hydrocortisone Cream 1% Drug Facts**

**Active ingredient**

Hydrocortisone 1%

**Purpose**

Anti-itch

**Uses**

- temporarily relieves itching associated with minor skin irritations, inflammation, and rashes due to:
  - eczema
  - insect bites
  - poison ivy, oak, or sumac
  - soaps
  - detergents
  - cosmetics
  - jewelry
  - seborrheic dermatitis
  - psoriasis
- temporarily relieves external anal and genital itching
- other uses of this product should only be under the advice and supervision of a doctor

**Warnings**

**For external use only**

**Do not use**

- in the genital area if you have a vaginal discharge. Consult a doctor.
- for the treatment of diaper rash. Consult a doctor.

**When using this product**

- avoid contact with eyes
- do not use more than directed unless told to do so by a doctor
- do not put directly into the rectum by using fingers or any mechanical device or applicator

**Stop use and ask a doctor if**

- rectal bleeding occurs
- condition worsens, symptoms persist for more than 7 days or clear up and occur again within a few days, and do not use this or any other hydrocortisone product unless you have asked a doctor

### **Keep out of reach of children.**

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

### **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: ask a doctor
- **for external anal and genital itching, adults:**
- when practical, cleanse the affected area with mild soap and warm water and rinse thoroughly
- gently dry by patting or blotting with toilet tissue or a soft cloth before applying
- apply to affected area not more than 3 to 4 times daily
- children under 12 years of age: ask a doctor

### **Other information**

- store at 20-25°C (68-77°F)

### **Inactive ingredients**

water, cetearyl alcohol, cetyl palmitate, glycerin, isopropyl myristate, isostearyl neopentanoate, cetareth-20, diazolidinyl urea, sorbic acid, aloe barbadensis leaf juice, BHT, sodium hydroxide

### **Questions or comments?**

**1-800-719-9260**

### **Principal Display Panel**

#1 DOCTOR RECOMMENDED ANTI-ITCH ACTIVE INGREDIENT

Relieves Itching and Redness Fast

- Maximum Strength
- Helps Heal Rashes for Healthier Skin

Hydrocortisone Cream 1%

Maximum Strength Anti-Itch Cream

NET WT 1 OZ (28g)

Padagis®

The image shows the front and side of a white cardboard box for Padagis Hydrocortisone Cream 1%. The top flap is light blue and features a cloud-shaped cutout. The main body of the box is white with a blue wave graphic at the bottom. The side of the box is black with a white target symbol and a barcode.

NDC 45802-438-03

**Relieves Itching and Redness Fast**

- Maximum Strength
- Helps Heal Rashes for Healthier Skin

**#1 DOCTOR RECOMMENDED**  
ANTI-ITCH ACTIVE INGREDIENT\*

**OTC via Rx**  
If a prescription is written for this product it may be covered by your health plan.

NDC 45802-438-03

**Hydrocortisone Cream 1%**  
Maximum Strength Anti-Itch Cream

NET WT 1 OZ (28g)

Padagis.

NDC 45802-438-03  
Hydrocortisone Cream 1%



<b>Drug Facts</b>	<b>Drug Facts (continued)</b>
<b>Active ingredient</b> Hydrocortisone 1%.....Anti-itch	<b>Purpose</b> Anti-itch
<b>Uses</b> <ul style="list-style-type: none"> <li>■ temporarily relieves itching associated with minor skin irritations, inflammation, and rashes due to:               <ul style="list-style-type: none"> <li>■ eczema    ■ insect bites    ■ poison ivy, oak, or sumac</li> <li>■ soaps    ■ detergents    ■ cosmetics</li> <li>■ jewelry    ■ seborrheic dermatitis    ■ psoriasis</li> </ul> </li> <li>■ temporarily relieves external anal and genital itching</li> <li>■ other uses of this product should be only under the advice and supervision of a doctor</li> </ul>	<b>Directions</b> <b>■ for itching of skin irritation, inflammation, and rashes:</b> <ul style="list-style-type: none"> <li>■ adults and children 2 years of age and older: apply to affected area not more than 3 to 4 times daily</li> <li>■ children under 2 years of age: do not use, ask a doctor</li> </ul> <b>■ for external anal and genital itching, adults:</b> <ul style="list-style-type: none"> <li>■ when practical, cleanse the affected area with mild soap and warm water and rinse thoroughly</li> <li>■ gently dry by patting or blotting with toilet tissue or a soft cloth before applying</li> <li>■ apply to affected area not more than 3 to 4 times daily</li> <li>■ children under 12 years of age: ask a doctor</li> </ul>
<b>Warnings</b> For external use only	<b>Other information</b> ■ store at 20-25°C (68-77°F)
<b>Do not use</b> <ul style="list-style-type: none"> <li>■ in the genital area if you have a vaginal discharge. Consult a doctor.</li> <li>■ for the treatment of diaper rash. Consult a doctor.</li> </ul>	<b>Inactive ingredients</b> water, cetearyl alcohol, cetyl palmitate, glycerin, isopropyl myristate, isostearyl neopentanoate, ceteareth-20, diazolidinyl urea, sorbic acid, aloe barbadensis leaf juice, BHT, sodium hydroxide
<b>When using this product</b> ■ avoid contact with eyes <ul style="list-style-type: none"> <li>■ do not use more than directed unless told to do so by a doctor</li> <li>■ do not put directly into the rectum by using fingers or any mechanical device or applicator</li> </ul>	<b>Questions or comments?</b> 1-800-719-9260
<b>Stop use and ask a doctor if</b> ■ rectal bleeding occurs <ul style="list-style-type: none"> <li>■ condition worsens, symptoms persist for more than 7 days or clear up and occur again within a few days, and do not use this or any other hydrocortisone product unless you have asked a doctor</li> </ul>	



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OTC 5, physicians surveyed by an independent market research firm.

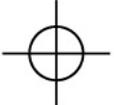
Manufactured for Padagis®  
 Minneapolis, MN 55427  
 www.padagis.com



Hydrocortisone Cream 1%

NDC 45802-438-03





<b>HYDROCORTISONE</b>			
hydrocortisone cream			
<b>Product Information</b>			
<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:45802-438
<b>Route of Administration</b>	TOPICAL		
<b>Active Ingredient/Active Moiety</b>			
<b>Ingredient Name</b>	<b>Basis of Strength</b>	<b>Strength</b>	
HYDROCORTISONE (UNII: W4X0X7BPJ) (HYDROCORTISONE - UNII:W4X0X7BPJ)	HYDROCORTISONE	1 g in 100 g	
<b>Inactive Ingredients</b>			
<b>Ingredient Name</b>	<b>Strength</b>		
WATER (UNII: 059QF0KO0R)			
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)			
POLYOXYL 20 CETOSTEARYL ETHER (UNII: YRC528SWUY)			
DIAZOLIDINYL UREA (UNII: H5RIZ3MPW4)			
SORBIC ACID (UNII: X045WJ989B)			
CETYL PALMITATE (UNII: 5ZA2S6B08X)			
GLYCERIN (UNII: PDC6A3C0OX)			

<b>ISOPROPYL MYRISTATE</b> (UNII: ORE8K4LNJS)	
<b>ISOSTEARYL NEOPENTANOATE</b> (UNII: 411THY156Q)	
<b>ALOE VERA LEAF</b> (UNII: ZY81Z83H0X)	
<b>BUTYLATED HYDROXYTOLUENE</b> (UNII: 1P9D0Z171K)	
<b>SODIUM HYDROXIDE</b> (UNII: 55X04QC32I)	

### Product Characteristics

<b>Color</b>	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:45802-438-03	1 in 1 CARTON	05/06/2011	
1		28 g in 1 TUBE; Type 0: Not a Combination Product		
2	NDC:45802-438-05	454 g in 1 JAR; Type 0: Not a Combination Product	05/10/2011	
3	NDC:45802-438-70	144 in 1 CARTON	09/01/2011	09/16/2015
3		.9 g in 1 PACKET; 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	05/06/2011	

**Labeler** - Padagis Israel Pharmaceuticals Ltd (600093611)