

## **UNISHIELD 1%- hydrocortisone cream**

### **Unishield**

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#### **49314-0005 Unishield Hydrocortisone**

#### **Active ingredient**

Hydrocortisone 1%

**Purpose** 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 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
- in eyes
- for feminine itching

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

- Keep out of eyes, ears, and mouth
- In case of contact with eyes, rinse eyes thoroughly with water

#### **Stop use and ask a doctor if**

condition worsens or lasts more than 7 days, or clears and occurs again within a few days

you begin use of other hydrocortisone product unless you have consulted a doctor

bleeding occurs

**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 12 years of age: for external anal itching, consult a doctor
- 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)
- Tamper evident, do not use any opened or torn packets

**Inactive ingredients**

cetearyl alcohol, cetareth-20, ethylhexylglycerin, glycerin, glycerol fatty acid ester, mineral oil, petrolatum, phenoxyethanol, water

<b>Drug Facts</b>		<b>Drug Facts (continued)</b>	
<b>Active ingredient</b>	<b>Purpose</b>	<ul style="list-style-type: none"> <li>■ you begin use of any other Hydrocortisone product unless you have consulted a doctor</li> <li>■ bleeding occurs</li> </ul>	
Hydrocortisone 1%.....	Anti-itch	<b>KEEP OUT OF REACH OF CHILDREN.</b> If swallowed, get medical help or contact a Poison Control Center right away.	
<b>Uses</b>		<b>Directions</b>	
<ul style="list-style-type: none"> <li>■ 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</li> <li>■ other uses of this product should be only under the advice and supervision of a doctor</li> </ul>		<ul style="list-style-type: none"> <li>■ for adults and children 2 years of age and older: apply to affected area 3 to 4 times daily</li> <li>■ children under 12 years of age: for external anal itching, consult a doctor</li> <li>■ children under 2 years of age: do not use, consult a doctor</li> <li>■ 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</li> </ul>	
<b>Warnings</b>		<i>(continued on side panel)</i>	
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Stop use and ask a doctor if			
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Distributed by: UniShield, San Fernando, CA 91340 • 1-800-480-5855  
Made in China

<b>UNISHIELD 1%</b>			
hydrocortisone cream			
<b>Product Information</b>			
<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:49314-0005
<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)			
GLYCERIN (UNII: PDC6A3C0OX)			

<b>POLYOXYL 20 CETOSTEARYL ETHER</b> (UNII: YRC528SWUY)	
<b>CETOSTEARYL ALCOHOL</b> (UNII: 2DMT128M1S)	
<b>ETHYLHEXYLGLYCERIN</b> (UNII: 147D247K3P)	
<b>MINERAL OIL</b> (UNII: T5L8T28FGP)	
<b>PETROLATUM</b> (UNII: 4T6H12BN9U)	
<b>PHENOXYETHANOL</b> (UNII: HIE492ZZ3T)	

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:49314-0005-1	25 in 1 BOX	11/15/2023	
1		0.9 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	11/15/2023	

**Labeler** - Unishield (790677053)

### Establishment

Name	Address	ID/FEI	Business Operations
Nantong Health & Beyond Hygienic Products Inc.		421280161	manufacture(49314-0005)

Revised: 11/2023

Unishield