

**HYDROCORTISONE - hydrocortisone cream**  
**NeoPharm Co., Ltd.**

*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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**Drug Facts**

**Active Ingredient**

Hydrocortisone 1%

**Purpose**

Anti-itch

**Uses**

temporarily relieves itching associated with minor skin irritation, inflammation and rashes due to:

- eczema
- psoriasis
- seborrheic dermatitis
- poison ivy, oak, sumac
- insect bites
- soaps and detergents
- cosmetics
- jewelry
- external feminine and anal itching

Other uses of this product: ask a doctor

**Warnings**

For external use only

**Do not use**

- in or near the eyes
- by putting directly into the rectum by using fingers or any mechanical device or applicator
- for external feminine itching if you have a vaginal discharge
- for diaper rash; ask a doctor

**Ask a doctor or pharmacist before use if you are**

using any other hydrocortisone product

**When using this product**

for external anal itching, do not exceed recommended daily dosage unless directed by a doctor

**Stop use and ask a doctor if**

- condition worsens or does not improve within 7 days
- symptoms clear up and return within a few days
- rectal bleeding occurs

**Keep out of reach of children**

If swallowed, get medical help or contact a Poison Control

**Directions**

- apply to affected area not more than 3 to 4 times daily
- for external anal itching: when practical, clean area with mild soap and warm water, rinse thoroughly, gently dry by patting or blotting with toilet tissue or a soft cloth before application of this product
- children under 2 years, or children under 12 years with external anal itching: do not use, ask a doctor

**Other information**

- store at room temperature, protect from freezing

Cetyl alcohol, Butylated hydroxytoluene, Glycerin, Glyceryl monostearate, Isopropyl myristate, Myristoyl/palmitoyl/oxostearamide/arachamide MEA, Methylparaben, PEG-15 glyceryl stearate, Squalane, Stearic acid, Propylparaben, Purified water

Hydrocortisone

MAXIMUM STRENGTH

NDC No. 68374-002-04  
**Pure-Aid™**

Compare to maximum strength Cortaid® active ingredient\*

# FAST RELIEF

**Itching**  **Redness**

Anti-Itch Cream for Skin Irritations



**KAREWAY**

MAXIMUM STRENGTH

1% Cream

# Hydrocortisone

Relieves Itching and Redness Fast!

NET 1 oz(28.3g)

1% Cream

**Hydrocortisone**  
Relieves Itching and Redness Fast!

1% Cream

# Hydrocortisone

Relieves Itching and Redness Fast!



LOT & EXP.

<p>Made in Korea</p> <p>Exclusively distributed by: Kareway Product Inc., Compton, CA 90220</p> <p>Healthcare, owner of the registered trademark Cortaid®</p> <p>*This product is not manufactured or distributed by Pharmacia Consumer</p>	
<p><b>Drug Facts</b></p> <p>Active ingredient Hydrocortisone 1.0%.....Anti-itch</p> <p><b>Purpose</b>.....Anti-itch</p> <p>Keep out of reach of children. If swallowed, get medical help or contact a Poison Control</p> <p><b>Directions</b></p> <p>Apply to affected area not more than 3 to 4 times daily for external anal itching; when practical, clean area with mild soap and warm water; rinse thoroughly, gently dry by patting or blotting with toilet tissue or a soft cloth before application of this product</p> <p>Children under 2 years, or children under 12 years with external anal itching; do not use, ask a doctor</p> <p><b>Other information</b></p> <p>Store at room temperature, protect from freezing</p> <p><b>Inactive ingredients</b> Cetyl alcohol, Butylated hydroxytoluene, Glycerin, Glyceryl monostearate, isopropyl myristate, Myristoylpalmitoyl oxostearamide/arachamide MEA, Methylparaben, Propylparaben, Purified water</p>	<p><b>Warnings</b></p> <p>For external use only</p> <p>Do not use in or near the eyes</p> <p>Do not use in or near the eyes by putting directly into the rectum by using fingers or any mechanical device or applicator</p> <p>For external feminine itching if you have a vaginal discharge</p> <p>For diaper rash; ask a doctor</p> <p>Ask a doctor or pharmacist before use if you are using any other hydrocortisone product</p> <p>When using this product for external anal itching, do not exceed recommended daily dosage unless directed by a doctor</p> <p>Stop use and ask a doctor if</p> <p>Condition worsens or does not improve within 7 days</p> <p>Symptoms clear up and return within a few days</p> <p>Rectal bleeding occurs</p>

**KAREWAY**

**Hydrocortisone**  
Relieves Itching and Redness Fast!

## HYDROCORTISONE

hydrocortisone cream

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:51141-0065
<b>Route of Administration</b>	TOPICAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>Hydrocortisone</b> (UNII: WI4X0X7BPJ) (Hydrocortisone - UNII:WI4X0X7BPJ)	Hydrocortisone	1 h in 100 g

### Inactive Ingredients

Ingredient Name	Strength
<b>Cetyl alcohol</b> (UNII: 936JST6JCN)	
<b>BUTYLATED HYDROXYTOLUENE</b> (UNII: 1P9D0Z171K)	
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	
<b>GLYCERYL MONOSTEARATE</b> (UNII: 230OU9XXE4)	
<b>ISOPROPYL MYRISTATE</b> (UNII: 0RE8K4LNJS)	
<b>METHYL PARABEN</b> (UNII: A2I8C7HI9T)	
<b>SQUALANE</b> (UNII: GW89575KF9)	
<b>STEARIC ACID</b> (UNII: 4ELV7Z65AP)	
<b>PROPYL PARABEN</b> (UNII: Z8IX2SC1OH)	
<b>WATER</b> (UNII: 059QF0KO0R)	

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:51141-0065-1	1 in 1 BOX		
1		28 g in 1 TUBE		
2	NDC:51141-0065-5	1 in 1 BOX		
2		14 g in 1 TUBE		

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	09/01/2010	

**Labeler** - NeoPharm Co., Ltd. (631101883)

**Registrant** - NeoPharm Co., Ltd. (631101883)

### Establishment

Name	Address	ID/FEI	Business Operations
NeoPharm Co., Ltd.		631101883	manufacture