

**ATOPALM MOISTURIZING 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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**ATOPALM Moisturizing Hydrocortisone Cream**

**Active Ingredient**

Hydrocortisone 1%

**Purpose**

Anti-itch

**Uses** for the temporary relief or itching associated with minor skin irritation, inflammation and rashes due to:

eczema

insect bites

poison ivy, poison oak, or poison sumac

soaps

detergents

jewelry

seborrheic dermatitis

psoriasis

external genital and anal itching 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. Consult a doctor

for external genital itching or if you have a vaginal discharge. Consult a doctor.

**When using this product**

avoid contact with the eyes

do not begin the use of any other hydrocortisone product unless you have consulted a doctor

for external anal itching do not exceed the recommended daily dosage unless directed by a doctor. In case of bleeding, consult a doctor promptly.

Do not put this product in rectum by using fingers or any mechanical devise for application.

**Stop use and ask a doctor if**

condition worsens or if symptoms persist for more than 7 days or clean up and then occur again within a

few days. Stop use and do not begin use of any other hydrocortisone products unless you have consulted a doctor. Do not exceed recommended daily dosage unless directed by a doctor.

**Ask a doctor or a pharmacist before** use if you are using any other hydrocortisone product.

**Keep out of reach of children.** If swallowed, get medical help or contact a Poison Control Center immediately.

### **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**

Do not use. Consult a doctor.

#### **For external anal 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 application of this product.

children under 12 years of age with external anal itching, consult a doctor.

### **Other Information**

store at room temperature

see end of carton or tube crimp for lot number and expiration date

**Inactive Ingredients** Water, Glycerin, Cetyl Alcohol, PEG-15 Glyceryl Stearate, Glyceryl Stearate, Isopropyl Myristate, Squalane, Stearic Acid, BHT, Cholesterol, Myristoyl/Palmitoyl Oxostearamide/Arachamide MEA, Methylparaben, Propylparaben

**Questions?** Call 1-855-ATOPALM

US Patent # US 6221371B1 Distributed by: NeoPharm Co., Ltd., 80 Wood Rd., #212 Camarillo, CA 93010 Made in Korea 75712 LOT and EXP.

Maximum Strength

plus US Patented Technology

1% Hydrocortisone

ATOPALM™

MOISTURIZING HYDROCORTISONE CREAM

WITH US PATENTED M L E TECHNOLOGY

Relieves Itching and Redness Fast!

Provides Temporary Relief and Visibly Healthier Looking Skin

Maximum Strength

medicine without a prescription for temporary relief of your worst itch symptoms.

ATOPALM™

Relieves itches due to: Dry Skin, Psoriasis, Seborrheic Dermatitis, Rashes

Net Wt. 1 oz/ 28.3 g

NDC 51141-6000-1



# Maximum Strength

- ✓ Relieves itching and redness fast!
- ✓ Provides temporary relief and visibly healthier looking skin
- ✓ Delivered in a moisturizing cream

Relieves Itches due to: Dry Skin, Psoriasis, Seborrheic Dermatitis, Rashes

## ATOPALM®

**Maximum Strength**  
Without a prescription

1% Hydrocortisone Moisturizing Anti-Itch Cream

# HYDROCORTISONE

Net Wt. 1 oz/28.3 g

ATOPALM®

**Maximum Strength**  
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ATOPALM®



# MOISTURIZING HYDROCORTISONE CREAM

ATOPALM®

## Drug Facts

**Active Ingredient**.....**Purpose**  
Hydrocortisone 1%.....Anti-itch

**Uses** for the temporary relief of itching associated with minor skin irritation, inflammation and rashes due to: ■ eczema ■ insect bites ■ poison ivy, poison oak, or poison sumac ■ soaps ■ detergents ■ jewelry ■ seborrheic dermatitis ■ psoriasis ■ external genital and anal itching. 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. Consult a doctor
- for external genital itching or if you have a vaginal discharge. Consult a doctor.

#### When using this product

- avoid contact with the eyes
- do not begin the use of any other hydrocortisone product unless you have consulted a doctor
- for external anal itching do not exceed the recommended daily dosage unless directed by a doctor. In case of bleeding, consult a doctor promptly
- Do not put this product in rectum by using fingers or any mechanical device for application.

#### Stop use and ask a doctor if

- condition worsens or if symptoms persist for more than 7 days or clear up and then occur again within a few days. Stop use and do not begin use of any other hydrocortisone products unless you have consulted a doctor. Do not exceed recommended daily dosage unless directed by a doctor.
- Ask a doctor or a pharmacist before use if you are using any other hydrocortisone product.

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center immediately. ▶

## Drug Facts (continued)

### 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

- Do not use. Consult a doctor

#### For external anal 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 application of this product
- children under 12 years of age with external anal itching, consult a doctor.

### Other Information

- store at room temperature
- see end of carton or tube crimp for lot number and expiration date.

### Inactive Ingredients

Water, Glycerin, Cetyl Alcohol, PEG-15 Glyceryl Stearate, Glyceryl Stearate, Isopropyl Myristate, Squalane, Stearic Acid, BHT, Cholesterol, Myristoyl/Palmitoyl Oxostearamide/Arachamide MEA, Methylparaben, Propylparaben

**Questions or information call toll free:** 1-855-ATOPALM

US Patent # US 6221371B1

Distributed by: NeoPharm USA, 1 Oyster Bay Drive, Rumson, NJ 07760

Made in Korea

75712

## ATOPALM MOISTURIZING HYDROCORTISONE

hydrocortisone cream

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:51141-6000
<b>Route of Administration</b>	TOPICAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
HYDROCORTISONE (UNII: W14X0 X7BPJ) (HYDROCORTISONE - UNII:W14X0 X7BPJ)	HYDROCORTISONE	1 g in 100 g

### Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
GLYCERIN (UNII: PDC6A3C0OX)	
PEG-15 GLYCERYL STEARATE (UNII: 91245SPD5K)	
ISOPROPYL MYRISTATE (UNII: 0RE8K4LNJS)	

<b>SQUALANE</b> (UNII: GW89575KF9)	
<b>STEARIC ACID</b> (UNII: 4ELV7Z65AP)	
<b>BUTYLATED HYDROXYTOLUENE</b> (UNII: 1P9D0Z171K)	
<b>CHOLESTEROL</b> (UNII: 97C5T2UQ7J)	
<b>METHYLPARABEN</b> (UNII: A2I8C7HI9T)	
<b>PROPYLPARABEN</b> (UNII: Z8IX2SC1OH)	
<b>MYRISTOYL/PALMITOYL OXOSTEARAMIDE/ARACHAMIDE MEA</b> (UNII: 1211AIM8G7)	

**Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:51141-6000-1	1 in 1 CARTON		
1		28.3 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	03/17/2011	

**Labeler** - NeoPharm Co., Ltd. (965502912)

**Establishment**

Name	Address	ID/FEI	Business Operations
NeoPharm Co., Ltd.		631101883	manufacture(51141-6000)

Revised: 6/2015

NeoPharm Co., Ltd.