

ATOPALM MAXIMUM STRENGTH ANTI-ITCH - hydrocortisone ointment
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.

Atopalm Maximum Strength Anti-Itch Ointment

Active Ingredient

Active Ingredient.....	Purpose
Hydrocortisone 1%.....	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, 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, 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 - symptoms persist for more than 7 days or clear up and occur again within a few
days.

Keep out of reach of children

Keep out of reach of children.

Other Safety Information

If swallowed, get medical help or call 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, or 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.

Storage & Handling

- store at 20° – 25°C (68° – 77°F) - see end of carton or tube crimp for lot number and expiration date

Inactive Ingredients

Petrolatum, Mineral Oil, Cetyl Alcohol, Stearic Acid, Beeswax, Myristoyl/Palmitoyl Oxostearamide/Arachamide MEA, Cholesterol, Methylparaben, Propylparaben

Questions or information

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

Purpose

Anti-Itch

Description

US Patent # US 6221371B1 Distributed by: Neopharm, USA, 1 Oyster Bay Drive, Rumson, NJ 07760
Made in Korea Batch/Lot # / Exp. Date

Maximum Strength Therapy available without a prescription Anti-Itch Ointment ATOPALM
MAXIMUM STRENGTH ANTI-ITCH OINTMENT US Patented M L E Moisturizing Technology
Net Wt. 1 oz /28.3 g 1% Hydrocortisone Active Ingredient Hydrocortisone 1% Uses: for the temporary relief of itching associated with minor skin irritations, inflammation and rashes due to eczema, insect bites, poison ivy, poison oak or poison sumac, soaps, detergents, 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, if you have a vaginal discharge, consult a doctor. When using this product - avoid contact with 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 into the rectum by using fingers or any mechanical devise or applicator. Stop use and ask a doctor if - condition worsens - symptoms persist for more than 7 days or clear up and occur again with a few days. Keep out of reach of children. If swallowed, get medical help or call a Poison Control Center immediately. Directions: Adults and children 2 years of age or 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, or 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 20° – 25°C (68° – 77°F) See end of carton or tube crimp for lot number and expiration date. Questions or information call toll free: 1-855 ATOPALM Distributed by: Neopharm, USA, 1 Oyster Bay Drive, Rumson, NJ 07760 Made in Korea #75722

Maximum Strength Therapy without a prescription 1% Hydrocortisone Anti-Itch Ointment ATOPALM MAXIMUM STRENGTH ANTI-ITCH OINTMENT US Patented M L E Moisturizing Technology Fast, temporary relief of pain, itching and redness from insect bites and skin irritations associated with Poison Ivy, Oak, Sumac, Eczema and Psoriasis. Leaves Skin Looking Visibly Healthier,

Softer, Smoother. Maximum Strength without a prescription ATOPALM RAPID RELIEF Rapid Relief of Itching and Redness

Rapid Relief of Itching and Redness ATOPALM MAXIMUM STRENGTH ANTI-ITCH OINTMENT US Patented M L E Moisturizing Technology Net Wt. 1 oz /28.3 g 1% Hydrocortisone ATOPALM MAXIMUM STRENGTH ANTI-ITCH OINTMENT US Patented M L E Moisturizing Technology 8 57811 00222 4 Rapid Relief Anti-Itch Ointment

ATOPALM RAPID RELIEF ANTI-ITCH OINTMENT Fast Temporary Relief of Pain and Itching from Insect Bites, Poison Ivy, Oak and Sumac, Psoriasis, External Genital and Anal Itching. US Patent # US 6221371B1 Distributed by: Neopharm, USA, 1 Oyster Bay Drive, Rumson, NJ 07760 Made in Korea 75722 Batch/Lot # / Exp. Date

Product Package Inner Label

Maximum Strength Therapy
available without a prescription

Anti-Itch Ointment

ATOPALM™

MAXIMUM STRENGTH ANTI-ITCH OINTMENT

US Patented **M L E** Moisturizing Technology



Net Wt. 1 oz /28.3 g

1% Hydrocortisone

Active Ingredient Hydrocortisone 1%

Uses: for the temporary relief of itching associated with minor skin irritations, inflammation and rashes due to eczema, insect bites, poison ivy, poison oak or poison sumac, soaps, detergents, seborrheic dermatitis, psoriasis, external genital and anal itching. Other uses of this product should be only under the advice and supervision of a doctor.

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

Made in Korea #75722

Product Package Outer Label 1

**Maximum Strength
Therapy**
without a prescription

1% Hydrocortisone
Anti-Itch Ointment

ATOPALM™
MAXIMUM STRENGTH ANTI-ITCH OINTMENT

US Patented **MLE** Moisturizing Technology



*Fast, temporary relief of pain, itching and redness from insect bites and skin irritations associated with Poison Ivy, Oak, Sumac, Eczema and Psoriasis.
Leaves Skin Looking Visibly Healthier, Softer, Smoother.*

Maximum Strength without a prescription

ATOPALM™
RAPID RELIEF

Rapid Relief of Itching and Redness

Product Package Outer Label 2



Product Package Outer Label 3

ATOPALM™

RAPID RELIEF ANTI-ITCH OINTMENT

Fast Temporary Relief of Pain and Itching from Insect Bites, Poison Ivy, Oak and Sumac, Psoriasis, External Genital and Anal Itching.

Drug Facts

Active Ingredient.....**Purpose**
Hydrocortisone 1%.....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, 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.

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- 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
- symptoms persist for more than 7 days or clear up and occur again within a few days.

Keep out of reach of children. If swallowed, get medical help or call 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, or by patting or blotting with toilet tissue or a soft cloth before application of this product.
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Questions or information call toll free: 1-855-ATOPALM

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Batch/Lot # / Exp. Date

ATOPALM MAXIMUM STRENGTH ANTI-ITCH

hydrocortisone ointment

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:51141-60 10
Route of Administration	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
PETROLATUM (UNII: 4T6 H12BN9 U)	
MINERAL OIL (UNII: T5L8 T28 FGP)	
CETYL ALCOHOL (UNII: 936 JST6 JCN)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
YELLOW WAX (UNII: 2ZA36H0S2V)	
MYRISTOYL/PALMITOYL OXOSTEARAMIDE/ARACHAMIDE MEA (UNII: 1211AIM8G7)	
CHOLESTEROL (UNII: 97C5T2UQ7J)	
METHYLPARABEN (UNII: A2I8C7HI9 T)	
PROPYLPARABEN (UNII: Z8IX2SC10H)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:51141-60 10-1	1 in 1 CARTON		
1		28.3 g in 1 TUBE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part348	11/04/20 11	

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

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

Revised: 11/2011

NeoPharm Co., Ltd.