

HYDROCORTISONE HC- 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.

Hydrocortisone 1%

Active Ingredient

Hydrocortisone 1%

Purpose

Anti-itch

Keep out of reach of children

if swallowed, get medical help or contact a Poison Control

Uses

temporarily relieves itching

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

- psoriasis
- seborrheic dermatitis
- poison ivy,oak,sumac
- insect bites

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 diaper rash; ask a doctor

Directions

- apply to affected area not more than 3 to 4 time daily
- for external anal itching: when practical, clean area with mild soap and warm

Inactive ingredients

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

Hydrocortosone

MAXIMUM STRENGTH

NDC No. 51141-0065-1

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.

Made in Korea

Drug Facts
 Active Ingredient Hydrocortisone 1.0%
 Purpose Anti-Itch
 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.
 Inactive Ingredients butylated hydroxytoluene, cetyl alcohol, glycerin, glyceryl monostearate, isopropyl myristate, methylparaben, propylparaben, purified water, squalane, and stearic acid.

Warnings
 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.

Uses
 Temporarily relieves itching associated with minor skin irritation, inflammation and rashes due to:
 Eczema
 Scabies
 Poison ivy, oak, sumac
 Insect bites
 Soaps and detergents
 Cosmetics
 External feminine and anal itching.
 Other uses of this product: ask a doctor.

Caution
 Avoid contact with eyes, nose, mouth, and other mucous membranes.

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Drug Facts (continued)

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Drug Facts (continued)

KAREWAY

Hydrocortisone

Relieves Itching and Redness Fast!

HYDROCORTISONE HC

hydrocortisone cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:51141-0002
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Hydrocortisone (UNII: WI4X0 X7BPJ) (Hydrocortisone - UNII:WI4X0 X7BPJ)	Hydrocortisone	1 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
Cetyl alcohol (UNII: 936JST6JCN)	
Glycerin (UNII: PDC6A3C0OX)	
Squalane (UNII: GW89575KF9)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:51141-0002-4	1 in 1 BOX		
1		25 g in 1 TUBE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	12/15/2010	

Labeler - Neopharm Co., Ltd (631101883)

Registrant - Neopharm Co., Ltd (631101883)

Establishment

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

Revised: 1/2011

Neopharm Co., Ltd