

HYDROCORTISONE 1%- hydrocortisone ointment
Trifecta Pharmaceuticals Usa Llc

Hydrocortisone Ointment 1% ANTIPRURITIC (Anti-Itch)

DRUG FACTS

Active ingredient

Hydrocortisone 1%

Purpose

Anti-Itch

Keep out of the reach of children.

If swallowed, get medical help or contact a Poison Control Center immediately.

Uses

temporary relieves itching associated with minor skin irritations, inflammation and rashes due to:

- eczema ● seborrheic dermatitis ● psoriasis ● insect bites ● poison ivy, oak, sumac
- soaps
- detergents ● cosmetics ● jewelry ● 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 ● avoid contact with the eyes

● do not put this product into the rectum by using fingers or any mechanical device or applicator

● Stop using this product and ask a doctor ● in case of bleeding

● if condition worsens, or if symptoms persist for more than 7 days or clear up and occur again within a few days

● before you begin using any other hydrocortisone product

Do not use this product and ask a doctor

● if you have a vaginal discharge ● before treating diaper rash ● before using on children under 2 years of age

For External Anal Itching Users: ● 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 device or applicator
- children under 12 years of age: consult a doctor

Before using any medication, read all label directions. Keep this carton. It contains important information.

Directions

- 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 applying.
- adults and children 12 years of age and older: apply to the affected area not more than 3 to 4 times daily.
- children under 12 years of age: Do not use, consult a doctor.

Inactive ingredients

Light Mineral Oil, Petrolatum

Other information

- to open: unscrew cap and pull tab to remove foil seal
- if seal has been broken, do not use this product. Return product to the Store where you bought it
- store at controlled room temperature 15°-30°C (59 °- 86 °F)

see carton or tube crimp for lot number and expiration date

MAXIMUM STRENGTH

Distributed by:

Trifecta Pharmaceuticals USA™

101 NE Third Avenue, Suite 1500

Ft. Lauderdale, FL 33301 USA

Product of PRC

Packaging

OUTER BOX

Hydrocortisone Ointment 1% ANTIPRURITIC (Anti-Itch)

MAXIMUM STRENGTH

Effective Relief Of Itches & Rashes Due To:
Eczema, Seborrheic Dermatitis, Psoriasis, Insect Bites •
• Poison Ivy, Oak, and Sumac • External Genital and Anal Itching
• Soaps • Cosmetics • Detergents • and more

Hydrocortisone Ointment 1% ANTIPRURITIC (Anti-Itch)

MAXIMUM STRENGTH

Net Wt. 1 oz. (28.4g)

FAST RELIEF ANTIPRURITIC (Anti-Itch) Hydrocortisone Ointment 1%

100% GUARANTEED

INNER TUBE

Hydrocortisone Ointment 1% ANTIPRURITIC (Anti-Itch)

MAXIMUM STRENGTH

Net Wt. 1 oz. (28.4g)

Active ingredient
Hydrocortisone 1%
Uses
temporarily relieves itching associated with minor skin irritations, inflammation and rashes due to: • eczema • seborrheic dermatitis • psoriasis • insect bites • poison ivy, oak, sumac • soaps • detergents • cosmetics • genital • 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 • avoid contact with the eyes • do not put this product into the rectum by using fingers or any mechanical device or applicator. Stop using this product and ask a doctor • in case of bleeding • or condition worsens, or if symptoms persist for more than 7 days or clear up and occur again within a few days • before you begin using any other hydrocortisone product
Do not use this product and ask a doctor if you have a vaginal discharge • before treating diaper rash • before using-

Purpose
Anti-Itch

on children under 2 years of age. Keep out of the reach of children. If swallowed, get medical help or contact a Poison Control Center immediately.
STOP: Before using any medication, read all label directions. Keep this carton. It contains important information.
Directions • 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 • adults and children 12 years of age and older: apply to the affected area not more than 3 to 4 times daily • children under 12 years of age: Do not use, consult a doctor.
To open: unscrew cap and pull tab to remove foil seal, and screw cap back onto tube.
Inactive ingredients Light Mineral Oil, Petrolatum store at controlled room temperature 15°-30°C (59°-86°F) see carton or tube crease for lot number and expiration date.

Distributed by: Trifecta Pharmaceuticals USA™ 101 NE Third Avenue, Suite 1500 FL Lauderdale, FL 33301 USA Product of PFC www.trifecta-pharma.com

HYDROCORTISONE 1%			
hydrocortisone ointment			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:69396-017
Route of Administration	TOPICAL		
Active Ingredient/Active Moiety			
	Ingredient Name	Basis of Strength	Strength
	HYDROCORTISONE (UNII: W4X0X7BPJ) (HYDROCORTISONE - UNII:W4X0X7BPJ)	HYDROCORTISONE	1 g in 100 g
Inactive Ingredients			

Ingredient Name	Strength
LIGHT MINERAL OIL (UNII: N6K5787QVP)	
PETROLATUM (UNII: 4T6H12BN9U)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69396-017-20	1 in 1 BOX	04/09/2016	
1		28.4 g in 1 TUBE; Type 0: Not a Combination Product		
2	NDC:69396-017-05	1 in 1 BOX	08/23/2016	
2		15 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 Drug	M017	04/09/2016	

Labeler - Trifecta Pharmaceuticals Usa Llc (079424163)

Revised: 12/2024

Trifecta Pharmaceuticals Usa Llc