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

ullet if you have a vaginal discharge ullet before treating diaper rash ullet 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

ullet 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		INNER TUBE
		COMPARE TO CORTIZONE+10* ACTIVE INGREDIENT* NDC: 69396-017-20		NDC: 69396-017-20 Hydrocortisone OINTMENT 1% ANTIPRURITIC (Anti-Itch)
	Eczema, S	Effective Itch & Rash Relief For ieborrheic Dermatitis, Psoriasis, Insect Bites		Net Wt. 1 oz. (28.49) MAXIMUM STRENGTH Active ingredient Purpose on children under? years of age. Keep out of the reach
		MAXIMUM STRENGTH		Hydrocortisone 1%Anti-Itch of children. If svallowed, get medical help or contact a Uses Iemporary relieves liching associated with minor skin irritations. STOP:Bidro suing any medication, read all label directions.
	Eczen • Poison Iv	ve Relief Of Itches & Rashes Due To: na, Seborrheic Dermatitis, Psoriasis, Insect Bites • y, Oak, and Sumac • External Genital and Anal Itching Soaps • Cosmetics • Detergents • and more		solution commute provides insections of the pole of the commute provides and the commute
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HYDROCORTISONE 1 hydrocortisone ointment	L%				
Product Information					
Product Type	HUMAN OTC DRUG	ltem Code (Source)		NDC:69396-017	
Route of Administration	TOPICAL				
Active Ingredient/Active	Moiety				
Ingre	edient Name		Basis of St	rength	Strength
HYDROCORTISONE (UNII: W4X0X7BPJ) (HYDROCORTISONE - UNII:W4X0X7BPJ)			HYDROCORTIS	ONE	1 g in 100 g
Inactive Ingredients					

		Strength		
LI	GHT MINERAL OI	L (UNII: N6K5787QVP)		
PE	TROLATUM (UNII	: 4T6H12BN9U)		
P	ackaging			
#	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		
M	larketing l	nformation		
	Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
	category	g M017	04/09/2016	Date

Labeler - Trifecta Pharmaceuticals Usa Llc (079424163)

Revised: 12/2024

Trifecta Pharmaceuticals Usa Llc