HYDROCORTISONE- hydrocortisone ointment
TRIFECTA PHARMACEUTICALS USA LLC

Hydrocortisone OINTMENT 1%

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, White Petrolatum

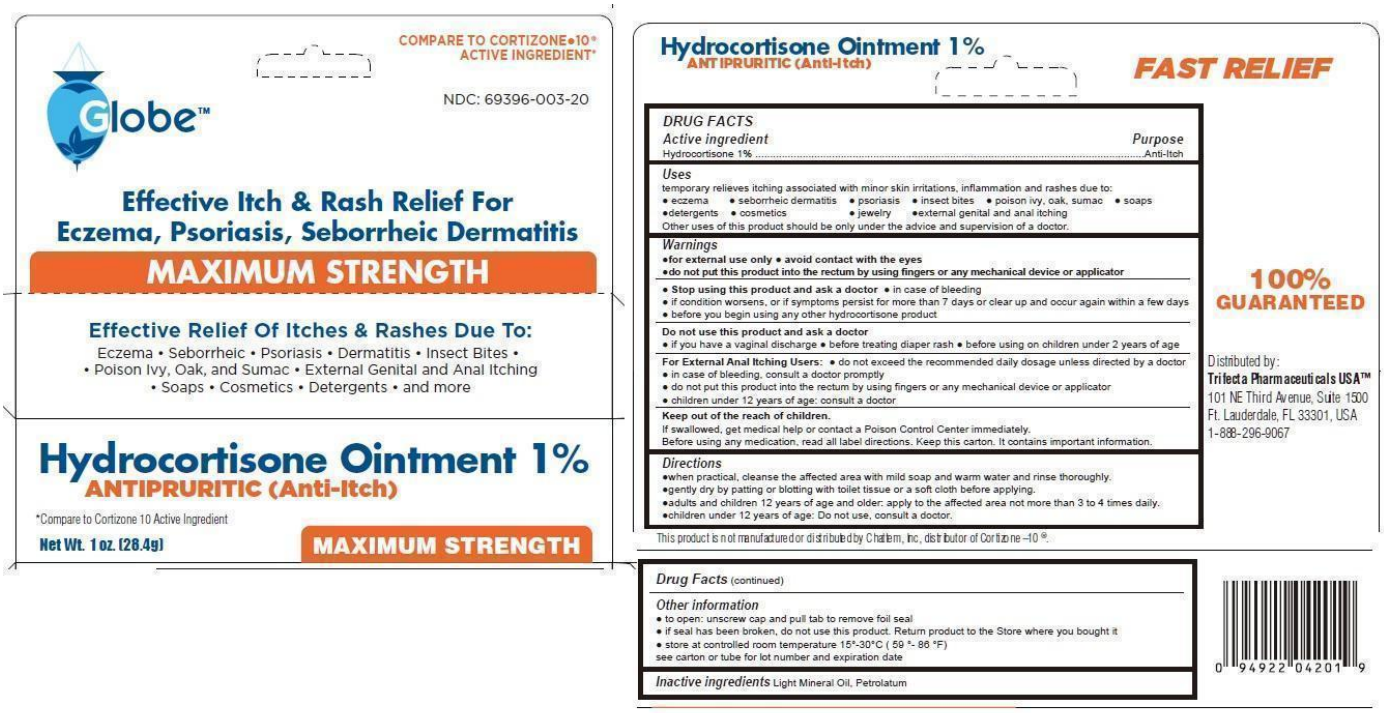
Other Information

- 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 for lot number and expiration date.

Distributed by:
Trifecta Pharmaceuticals USA™
101 NE Third Avenue, Suite 1500
Ft. Lauderdale, FL 33301, USA
1-888-296-9067

Packaging



HYDROCORTISONE

hydrocortisone ointment

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:69396-003
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)	

Product Characteristics			
Color	white	**Score**	
Shape		**Size**	
Flavor		**Imprint Code**	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69396-003-20	1 in 1 BOX	06/15/2017	
1		28.4 g in 1 TUBE; Type 0: Not a Combination Product		
2	NDC:69396-003-44	4 in 1 BOX	02/28/2024	
2		28.4 g in 1 TUBE; Type 0: Not a Combination Product		
3	NDC:69396-003-33	3 in 1 BOX	02/29/2024	
3		28.4 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	03/10/2015	

Labeler - TRIFECTA PHARMACEUTICALS USA LLC (079424163)

Registrant - Trifecta Pharmaceuticals USA (079424163)

Revised: 2/2024 TRIFECTA PHARMACEUTICALS USA LLC