HYDROCORTISONE- hydrocortisone ointment
TRIFECTA PHARMACEUTICALS USA LLC

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 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

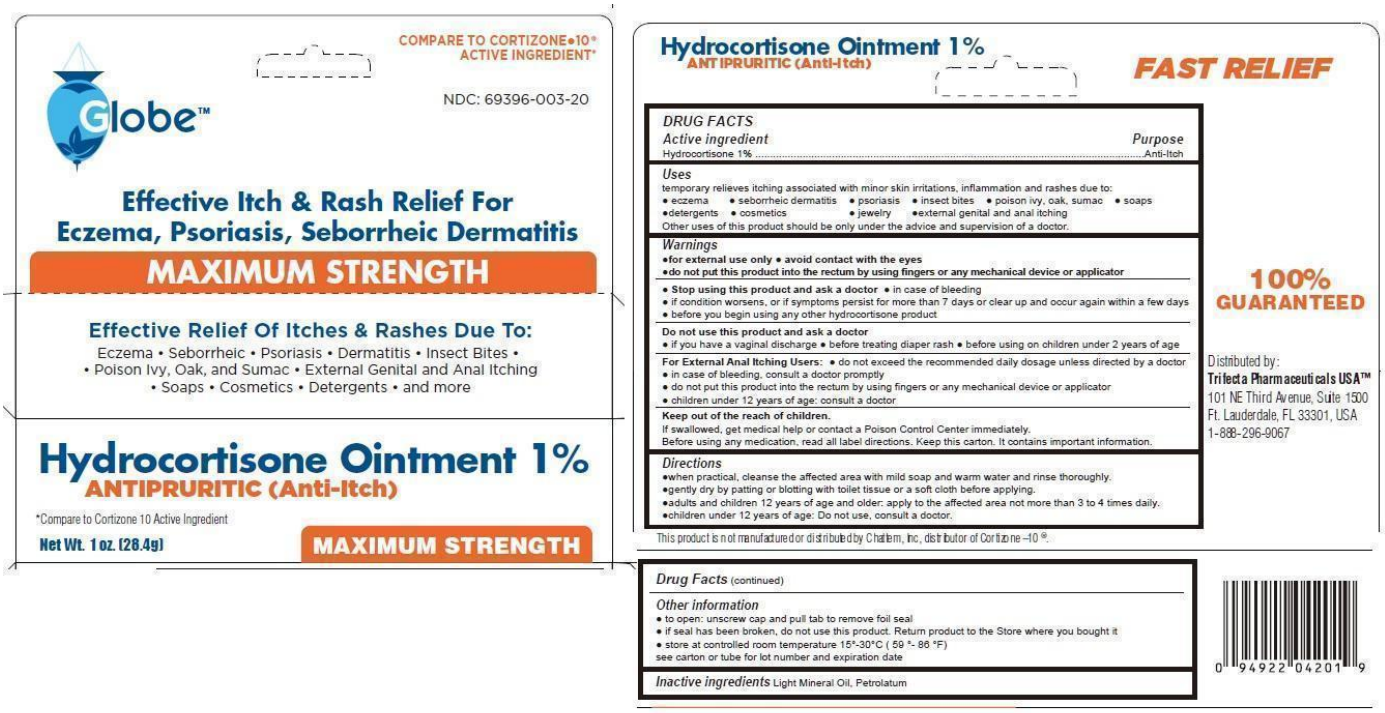
Other Information

- 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: WI4X0X7BPJ) (HYDROCORTISONE - UNII:WI4X0X7BPJ)	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		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	03/10/2015	

Labeler - TRIFECTA PHARMACEUTICALS USA LLC (079424163)

Registrant - Trifecta Pharmaceuticals USA (079424163)

Revised: 11/2017 TRIFECTA PHARMACEUTICALS USA LLC