

HYDROCORTISONE 1%- hydrocortisone cream
Trifecta Pharmaceuticals Usa Llc

Globe Hydrocortisone Cream 1%

MAXIMUM STRENGTH

DRUG FACTS

Active ingredient

Hydrocortisone 1%

Purpose

Antipruritic (Anti-Itch)

Keep out of the reach of children.

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

Uses

For temporary relief of itching associated with minor skin irritations and rashes

- external feminine, genital and anal itching

Other uses of this product should be only under the advice and supervision of a doctor

Do Not Use

- For the treatment of diaper rash, consult a doctor.
- With any other Hydrocortisone product unless you have consulted a doctor

- If you have a vaginal discharge, consult a doctor

Warnings

For external use only

When using this product

- Avoid Contact with the eyes
- do not exceed the recommended daily dosage unless directed by a doctor.
- 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 if

- conditions worsens, symptoms persist for more than 7 days or symptoms clear up and reappear again within a few days and do not begin use of any other hydrocortisone product.
- Rectal bleeding occurs

Directions

Adults and children 2 years of age and older: apply to the affected area not more than 3 to 4 times daily.

Children under 2 years of age: do not use and ask a doctor.

For External and anal itching in adults:

When practical, clean 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

For External anal and genital itching in children under 12 years of age:

Ask a doctor

Inactive ingredients

Cetareth-20, Cetearyl alcohol, Ethylhexylglycerin, Glycerin, Glyceryl Stearate, mineral oil, petrolatum, Phenoxyethanol, water.

Other information

- store at controlled room temperature 20°-25°C (68 °- 77 °F)

Tamper evident, do not use if packet is torn, cut or opened.

Avoid excessive heat and humidity.

Distributed by:

Trifecta Pharmaceuticals USA™

Ft. Lauderdale, FL 33301 USA

Online: www.trifecta-pharma.com

Reorder No. 1016SL

To reorder call: 1-888-296-9067

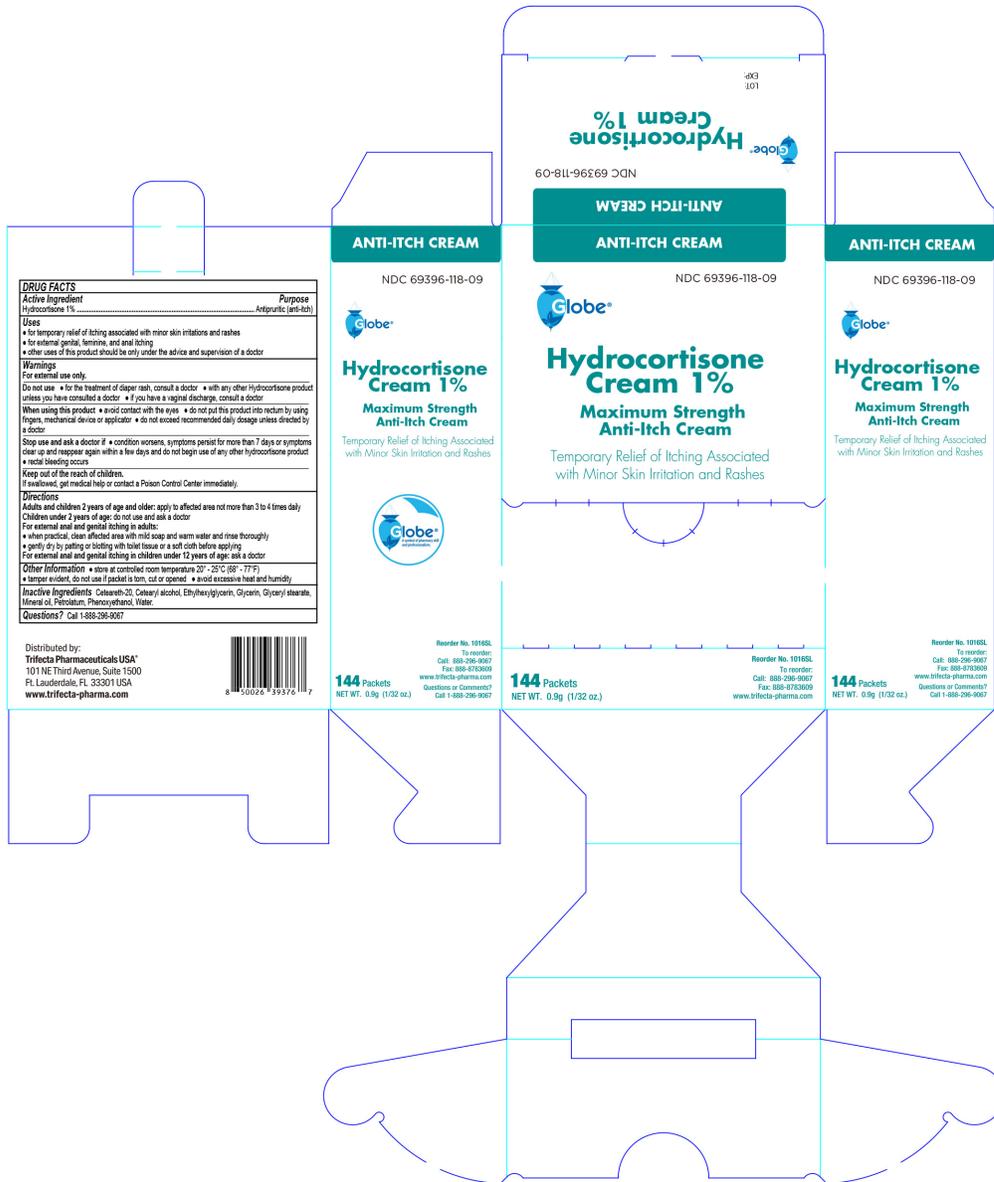
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Questions

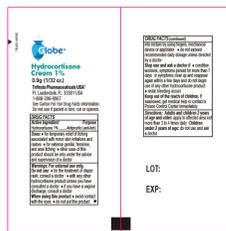
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LABEL

OUTSIDE BOX

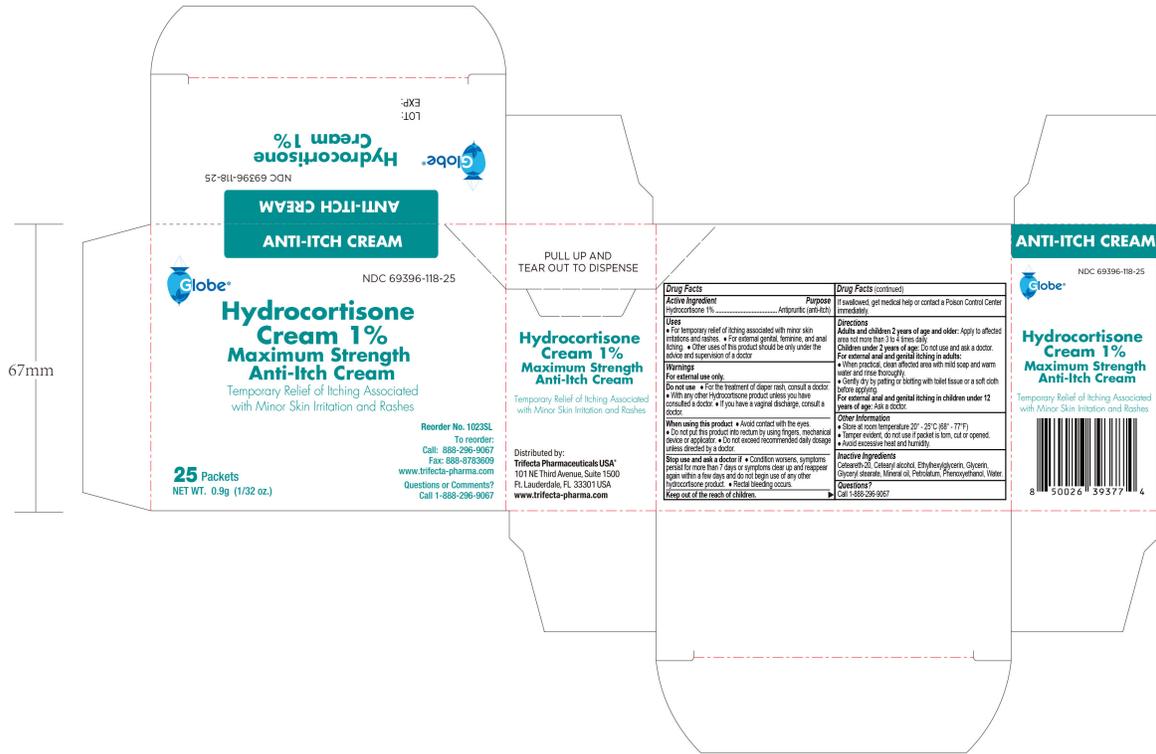


PACKET



Packaging

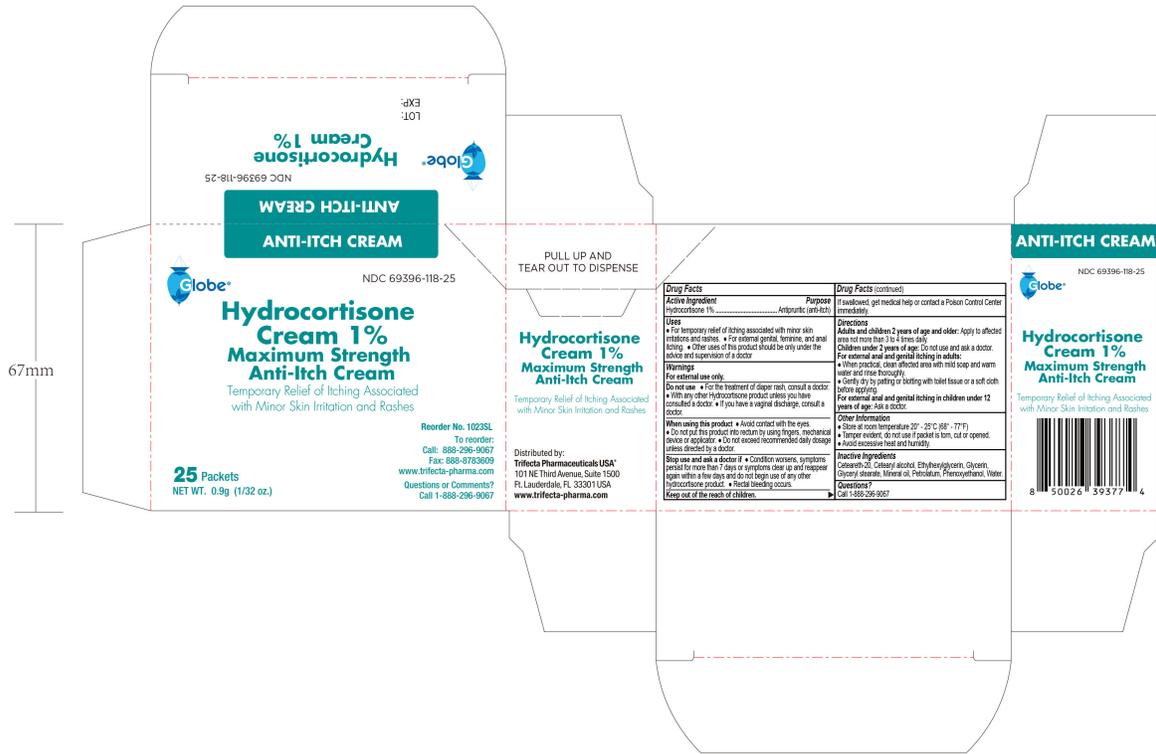
OUTSIDE BOX



INNER PACKET



OUTSIDE BOX



INNER PACKET



HYDROCORTISONE 1%

hydrocortisone cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:69396-118
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
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
MINERAL OIL (UNII: T5L8T28FGP)	
GLYCERIN (UNII: PDC6A3C0OX)	
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	
PETROLATUM (UNII: 4T6H12BN9U)	
WATER (UNII: 059QF0KO0R)	
POLYOXYL 20 CETOSTEARYL ETHER (UNII: YRC528SWUY)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69396-118-09	144 in 1 CARTON	05/31/2023	
1		0.9 g in 1 PACKET; Type 0: Not a Combination Product		
2	NDC:69396-118-25	25 in 1 BOX	05/31/2023	
2		0.9 g in 1 PACKET; 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	05/31/2023	

Labeler - Trifecta Pharmaceuticals Usa Llc (079424163)

