

**HYDROCORTISONE 1%- hydrocortisone cream**  
**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.*

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**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](http://www.trifecta-pharma.com)**

**Reorder No. 1016SL**

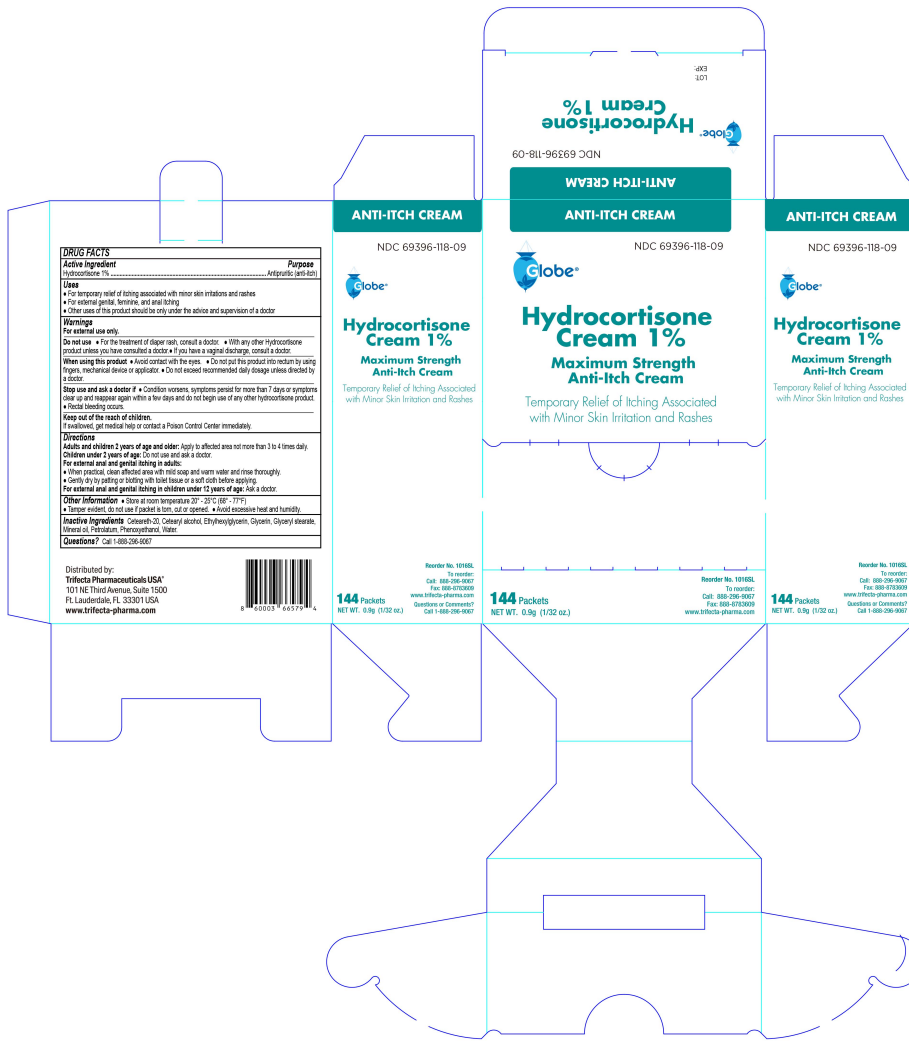
**To reorder call: 1-888-296-9067**

**Fax: 888-878-3609**

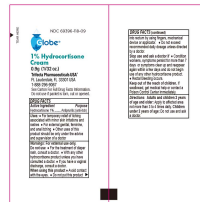
### **Questions**

Call 1-888-296-9067

# OUTSIDE BOX



# PACKET



hydrocortisone cream

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:69396-118
<b>Route of Administration</b>	TOPICAL		

### Active Ingredient/Active Moiety

<b>Ingredient Name</b>	<b>Basis of Strength</b>	<b>Strength</b>
<b>HYDROCORTISONE</b> (UNII: W4X0X7BPJ) (HYDROCORTISONE - UNII:W4X0X7BPJ)	HYDROCORTISONE	1 g in 100 g

### Inactive Ingredients

<b>Ingredient Name</b>	<b>Strength</b>
<b>PHENOXYETHANOL</b> (UNII: HIE492ZZ3T)	
<b>MINERAL OIL</b> (UNII: T5L8T28FGP)	
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	
<b>GLYCERYL MONOSTEARATE</b> (UNII: 230OU9XXE4)	
<b>PETROLATUM</b> (UNII: 4T6H12BN9U)	
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>POLYOXYL 20 CETOSTEARYL ETHER</b> (UNII: YRC528SWUY)	
<b>CETOSTEARYL ALCOHOL</b> (UNII: 2DMT128M1S)	
<b>ETHYLHEXYLGLYCERIN</b> (UNII: 147D247K3P)	

### Packaging

<b>#</b>	<b>Item Code</b>	<b>Package Description</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
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

<b>Marketing Category</b>	<b>Application Number or Monograph Citation</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
OTC monograph not final	part348	05/31/2023	

**Labeler** - Trifecta Pharmaceuticals Usa Llc (079424163)