

HYDROCORTISONE- hydrocortisone ointment

Moore Medical 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 Cream

First Aid

Drug Facts

Active Ingredient

Hydrocortisone 1%

Purpose

Anti-itch

Uses:

- for the temporary relief of itching associated with minor skin irritations, inflammation and rashes due to eczema, insect bites, poison ivy, poison oak, poison sumac, soaps, detergents, cosmetics, jewelry, seborrheic dermatitis, psoriasis and scrapes
- for external genital, feminine and anal itching
- other uses of this product should be only under the advice and supervision of a doctor

Warnings

- **For external use only**
- **Do not use** for the treatment of diaper rash

Ask a doctor before use:

- if you have a vaginal discharge (for external feminine itching)
- for external itching, do not exceed the recommended daily dosage, or if bleeding occurs
- if condition worsens or if symptoms persist for more than 7 days or clear up and occur again within a few days

When using this product

- avoid contact with eyes
- do not put this product into rectum by using fingers or any mechanical device or applicator

Do not use:

- with any other Hydrocortisone product unless you have consulted a doctor

KEEP OUT OF REACH OF CHILDREN.

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

Directions:

- for adults and children 2 years of age and older: apply to affected area 3 to 4 times daily
- children under 2 years of age: do not use, consult a doctor
- adults for external anal itching when practical, cleanse the affected area with mild soap and warm

water and rinse thoroughly or by patting or blotting with an appropriate cleansing pad

- gently dry by patting or blotting with toilet tissue or a soft cloth before application of this product
- children under 12 years of age: for external anal itching, consult a doctor

Other Information:

- store at room temperature (do not freeze)
- tamper evident sealed packets
- do not use any opened or torn packets

Inactive ingredients :

emulsifying wax, ethanol, methylparaben, mineral oil, paraffin, petrolatum, propylparaben, purified water, white wax

Questions or Comments? 1-800-234-1464

PRINCIPAL DISPLAY PANEL – 144 count box

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Supporting Health & Care

Reorder No. 82464

UPN# 0-0607415-82464-3

MooreBrand

Hydrocortisone

Cream 1%

144 Packets

Each Packet Net. Wt. 1.0gm

**Temporary relief of itching
associated with minor skin irritation,
inflammation and rashes.**

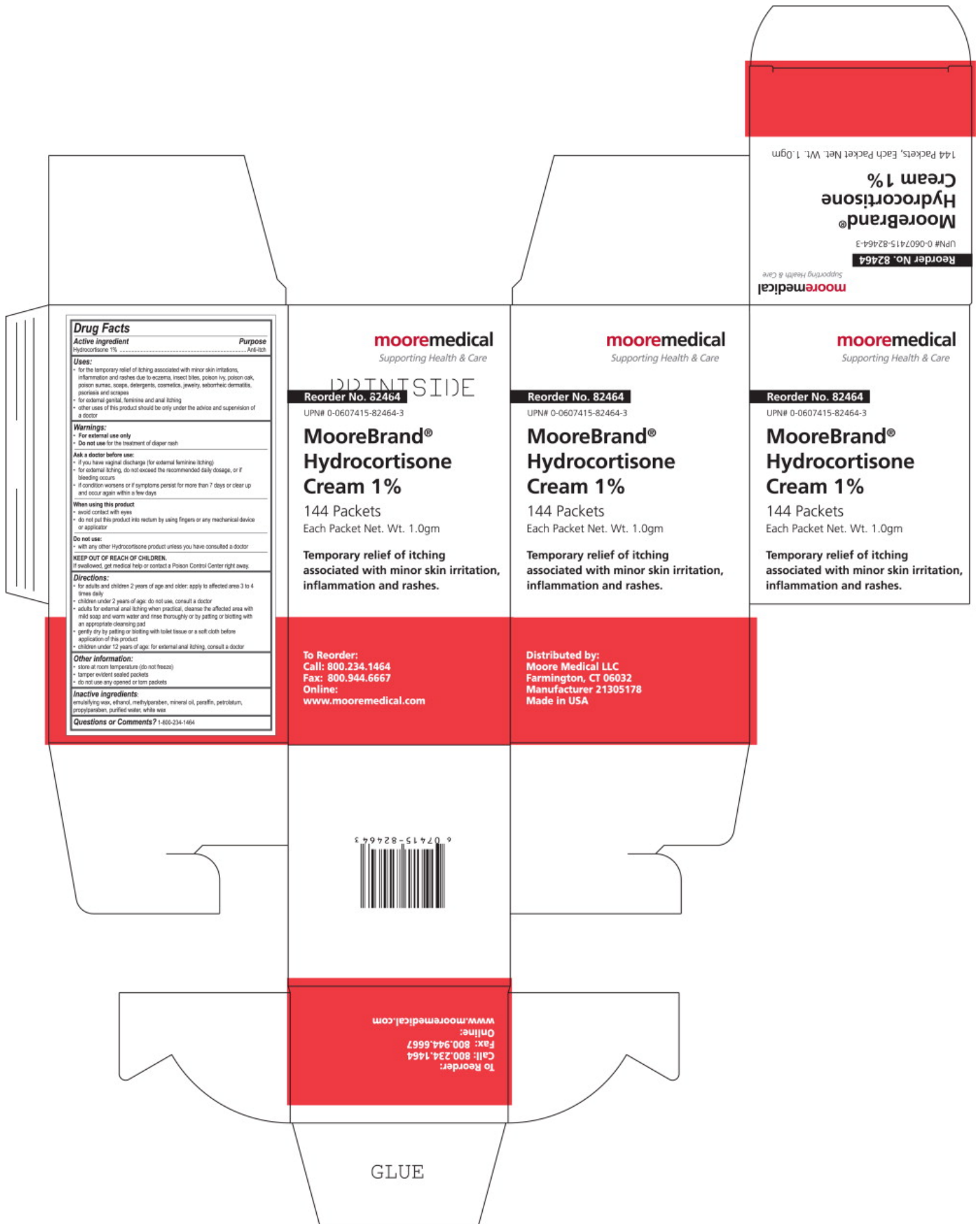
To reorder:

Call: 1-800-234-1464

Fax: 1-800-944-6667

Online:

www.mooremedical.com



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DIPTNTSIDE
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Distributed by:
Moore Medical LLC
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Manufacturer 21305178
Made in USA

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GLUE

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Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:55670-800
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Hydrocortisone (UNII: WI4X0 X7BPJ) (Hydrocortisone - UNII:WI4X0 X7BPJ)	Hydrocortisone	10 mg in 1 g

Inactive Ingredients

Ingredient Name	Strength
alcohol (UNII: 3K9958V90M)	
methylparaben (UNII: A2I8C7HI9T)	
mineral oil (UNII: T5L8T28FGP)	
paraffin (UNII: I9O0E3H2ZE)	
petrolatum (UNII: 4T6H12BN9U)	
propylparaben (UNII: Z8IX2SC1OH)	
water (UNII: 059QF0KO0R)	
white wax (UNII: 7G1J5DA97F)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:55670-800-01	144 in 1 BOX		
1		1.0 g in 1 PACKET		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	07/12/2012	

Labeler - Moore Medical LLC (051420107)**Registrant** - Safetec of America, Inc. (874965262)**Establishment**

Name	Address	ID/FEI	Business Operations
Safetec of America, Inc.		874965262	MANUFACTURE(55670-800)