

HYDROCORTISONE- hydrocortisone lotion

Mericon Industries

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

Drug Facts

Active Ingredient

Hydrocortisone 1%

Purpose

Anti-itch

Uses

For the temporary relief 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**

Stop using this product and ask a doctor

- 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

Keep this and all drugs out of the reach of children

Directions

- Adults and children 2 years of age and older: apply to affected area not more than 3 to 4 times daily
- Children under 2 years of age: do not use, consult a doctor

For External Anal Itching Users

- adults: when practical, cleanse the affected area with mild soap and warm water and rinse thoroughly, and gently dry by patting or blotting with toilet tissue or a soft cloth before application of this product
- children under 12 years of age: consult a doctor

Other Information

- store at 55 to 76F

Inactive Ingredients

stearic acid, propylene glycol, lanolin alcohol in mineral oil, isopropyl in myristate, cetyl alcohol, mono- and di-glycerides, polysorbate 80, sorbitan monooleate, a scent and purified water preserved with methylparaben and propylparaben.

PRINCIPAL DISPLAY PANEL - 114 g Bottle Label

0394-0859-32

Mericon Industries, Inc.

Hydrocortisone 1%
Lotion

Anti-Itch
Poison Ivy
Poison Oak
Poison Sumac
Hives • Rashes

Net Wt. 4 oz. (114g)

Drug Facts

Active Ingredient

Hydrocortisone 1%

Purpose

Anti-Itch

Uses: For the temporary relief 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

Stop using this product and ask a doctor

• 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

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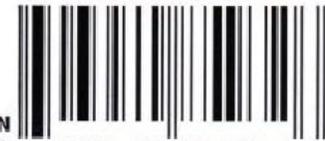
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Peoria, Illinois 61615
800-242-6464
mericonindustries.com

Net Wt. 4 oz. (114g)

HYDROCORTISONE

hydrocortisone lotion

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:0394-0859
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Hydrocortisone (UNII: W4X0X7BPJ) (Hydrocortisone - UNII:W4X0X7BPJ)	Hydrocortisone	1.14 g in 114 g

Inactive Ingredients

Ingredient Name	Strength
stearic acid (UNII: 4ELV7Z65AP)	
propylene glycol (UNII: 6DC9Q167V3)	
lanolin alcohols (UNII: 884C3FA9HE)	
mineral oil (UNII: T5L8T28FGP)	
MYRISTIC ACID (UNII: 0I3V7S25AW)	
cetyl alcohol (UNII: 936JST6JCN)	
polysorbate 80 (UNII: 6OZP39ZG8H)	
sorbitan monooleate (UNII: 06XEA2VD56)	
water (UNII: 059QF0K00R)	
methylparaben (UNII: A2I8C7HI9T)	
propylparaben (UNII: Z8IX2SC1OH)	

Product Characteristics

Color	WHITE	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0394-0859-32	12 in 1 BOX	06/12/2023	
1		114 g in 1 BOTTLE, DISPENSING; 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	06/12/2023	

Labeler - Mericon Industries (059943670)

Establishment

Name	Address	ID/FEI	Business Operations
Mericon Industries		059943670	MANUFACTURE(0394-0859)

Revised: 6/2023

Mericon Industries