QUALITY CHOICE ITCH RELIEF- hydrocortisone cream Chain Drug Marketing Association Inc.

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.

QC 1% Hydrocortisone Cream Max. Strength 1 oz 99260 (2019)

Active ingredient Purpose

Hydrocortisone 1%......Anti-itch

Uses

- temporarily relieves itching associated with minor skin irritation, inflammation, and rashed due to
- eczema
- psoriasis
- jewelry
- insect bites
- soaps
- cosmetics
- detergents
- seborrheic dermatitis
- poison ivy, oak sumac

Warnings

For external use only

Do not use

- in the genital area if you have a vaginal discharge. Consult a doctor.
- for the treatment of diaper rash. Consult a doctor.
- more than directed unless directed by a doctor

When using this product

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

Stop use and ask a doctor

- condition worsens, symptoms persist for more than 7 days or clear up and occur again within a few days, and do not begin use of any other hydrocortisone product unless you have asked a doctor
- rectal bleeding occurs

If pregnant or breast-feeding, ask a health professional before use.

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center (1-800-222-1222) right away.

Directions

- for itching of skin irritation, inflammation, and rashes:
- 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: ask a doctor
- for external anal and genital itching, adults:
- when practical, clean 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
- apply to affected area not more than 3 to 4 times daily

• children under 12 years of age: ask a doctor

Other information

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

Inactive ingredients

butylated hydroxytoluene, cetostearyl alcohol, light mineral oil, methylparaben, propylene glycol, propylparaben, purified water, sorbitan monooleate, steareth-20, stearic acid

Distributed by:

C.D.M.A., Inc.

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Novi, MI 48375

www.qualitychoice.com

Made in China



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hydrocortisone cream

Product Information

Product TypeHUMAN OTC DRUGItem Code (Source)NDC:63868-603

Active Ingredient/Active Moiety Ingredient Name Basis of Strength HYDROCORTISONE (UNII: WI4X0X7BPJ) (HYDROCORTISONE - UNII:WI4X0X7BPJ) HYDROCORTISONE 1 g in 100 g

Inactive Ingredients	
Ingredient Name	Strength
LIGHT MINERAL OIL (UNII: N6K5787QVP)	
METHYLPARABEN (UNII: A2I8 C7HI9 T)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
SORBITAN MONOOLEATE (UNII: 06 XEA2 VD56)	
STEARETH-20 (UNII: L0Q8IK9E08)	
BUTYLATED HYDRO XYTO LUENE (UNII: 1P9 D0 Z171K)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
STEARIC ACID (UNII: 4ELV7Z65AP)	

Packaging			
# Item Code	Package Description	Marketing Start Date	Marketing End Date
1 NDC:63868-603-28	1 in 1 CARTON	07/15/2019	
1	28 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	07/15/2019			

Labeler - Chain Drug Marketing Association Inc. (011920774)

Revised: 12/2019 Chain Drug Marketing Association Inc.