# TOPCARE HYDROCORTISONE- hydrocortisone ointment Topco Associates 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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# Topco Associates LLC. Hydrocortisone 1% Ointment Drug Facts

# **Active ingredient**

Hydrocortisone 1%

# Purpose

Anti-itch

#### Uses

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

#### **Warnings**

#### For external use only

#### Do not use

- in the genital area if you have a vaginal discharge. Ask a doctor.
- for the treatment of diaper rash. Ask a doctor.

#### When using this product

- avoid contact with the eyes
- do not use more than directed unless told to do so by a doctor
- do not put directly into the rectum by using fingers or any mechanical device or applicator

## Stop use and ask a doctor if

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

# Keep out of reach of children.

If swallowed, get medical help or contact a Poison Control Center 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: do not use, 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 20°-25°C (68°-77°F)

# **Inactive ingredients**

aloe barbadensis leaf juice, white petrolatum

# Questions or comments?

1-888-423-0139

## Package/Label Principal Display Panel

COMPARE TO CORTIZONE•10® ACTIVE INGREDIENT

Itch & Rash Relief Ointment

Relief of Skin Irritation, Rashes, Inflammation, Itching & Redness

MAXIMUM STRENGTH

**OUR PHARMACISTS RECOMMEND** 

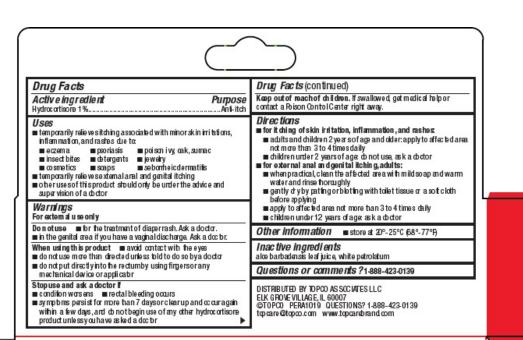
Hydrocortisone 1% Ointment

ANTI-ITCH OINTMENT

Ointment

NET WT 1 OZ (28 g)







Scan here for more information



\*This product is not manufactured or distributed by Chattem, Inc., distributor of Cortizone•10®.





#### TOPCARE HYDROCORTISONE

hydrocortisone ointment

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:36800-471
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
HYDRO CORTISONE (UNII: WI4X0 X7BPJ) (HYDROCORTISONE - UNII:WI4X0 X7BPJ)	HYDROCORTISONE	1 g in 100 g	

Inactive Ingredients		
Ingredient Name	Strength	
ALOE VERA LEAF (UNII: ZY81Z83H0X)		
PETROLATUM (UNII: 4T6 H12BN9 U)		

Product Characteristics			
Color	WHITE	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

	Packaging			
l	# Item Code	Package Description	<b>Marketing Start Date</b>	Marketing End Date
l	1 NDC:36800-471-64	1 in 1 CARTON	04/03/2020	
	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	04/03/2020	

# Labeler - Topco Associates LLC (006935977)

Revised: 4/2020 Topco Associates LLC