THERACARE MAXIMUM STRENGTH 1% HYDROCORTISONEhydrocortisone cream Veridian Healthcare

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.

TheraCare Maximum Strength 1% Hydrocortisone Cream

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.
- for the treatment of diaper rash.
- with any other hydrocortisone product unless you have asked a doctor

When using this product

- use only as directed
- avoid contact with 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. (1-800-222-1222)

Directions

- for itching of skin irritation, inflammation, and rashes:
- adults and children 2 years of age and over: apply to affected area not more than 3 to 4 times daily
- children under 2 years of age: consult a physician
- for external anal and genital itching, adults and children 12 years of age and over:
 - 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: consult a physician

Other information

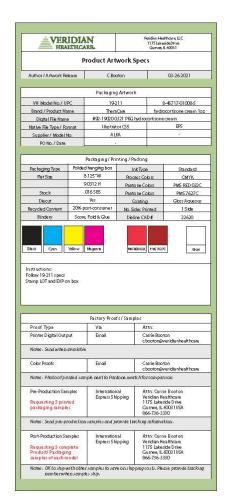
Store at 20-25C (68-77F)

do not use if tube seal under cap is broken

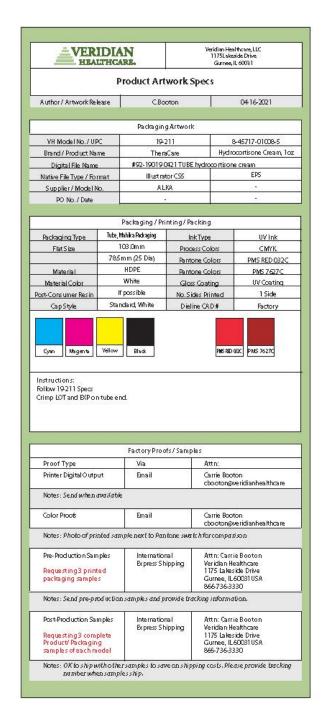
Inactive Ingredients

cetostearyl alcohol, edetate sodium, glyceryl monostearate, methylparaben, mineral oil, petrolatum, polysorbate 60, propylene glycol, propylparaben, sorbitan monostearate water.

TheraCare Maximum Strength 1% Hydrocortisone Cream







19-211 Hydrocortisone Cream, 1 oz

TUBE DIELINE

Scale: 100% (do not adjust)



THERACARE MAXIMUM STRENGTH 1% HYDROCORTISONE

hydrocortisone cream

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:71101-211
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	Basis of Strength	Strength

Inactive Ingredients		
Ingredient Name	Strength	
SORBITAN MONOSTEARATE (UNII: NVZ 410H58X)		
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)		
GLYCERYL MONOSTEARATE (UNII: 2300U9XXE4)		
METHYLPARABEN (UNII: A2I8C7HI9T)		
MINERAL OIL (UNII: T5L8T28FGP)		
PETROLATUM (UNII: 4T6H12BN9U)		
PROPYLPARABEN (UNII: Z8IX2SC1OH)		
WATER (UNII: 059QF0KO0R)		
EDETATE SODIUM (UNII: MP1J8420LU)		
POLYSORBATE 60 (UNII: CAL22UVI4M)		
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)		

I	Packaging				
7	# Item Code	Package Description	Marketing Start Date	Marketing End Date	
:	NDC:71101-211-	1 in 1 CARTON	05/01/2021		
:	L	28.3 g in 1 TUBE; Type 0: Not a Combination Product			

	Marketing Information			
Application Number or Monograph Citation	Marketing Start Date	Marketing End Date		
t348	05/01/2021			
	Citation	Citation Date		

Labeler - Veridian Healthcare (830437997)

Establishment				
Name	Address	ID/FEI	Business Operations	
Anicare Pharmaceuticals Private Limited		916837425	manufacture(71101-211)	

Revised: 5/2021 Veridian Healthcare