

**THERACARE MAXIMUM STRENGTH 1% HYDROCORTISONE-  
hydrocortisone 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.*

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**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***

		Veridian Healthcare, LLC 1175 Lakeside Drive Gurnee, IL 60031	
<b>Product Artwork Specs</b>			
Author / Artwork Release	C.Booton	03-26-2021	
<b>Packaging Artwork</b>			
VH Model No. / UPC	19211	8-4217-01008-6	
Brand / Product Name	TheraCare	hydrocortisone cream 1oz	
Digital File Name	#92-1910-0321 PKG hydrocortisone cream		
Native File Type / Format	Illustrator CS5	BPS	
Supplier / Model No.	AUSA	-	
PO No. / Date	-	-	
<b>Packaging / Printing / Packing</b>			
Packaging Type	Folded hanging box	Ink Type	Standard
Part Size	8.125" W	Process Color	CMYK
Stock	90312 H	Process Color	PMS 867-032C
Diect	01658S	Process Color	PMS 75272C
Recycled Content	Yes	Coating	Gloss Aqueous
Binding	20% post-consumer	No. Side Printed	1 Side
	Score, Fold & Glue	Dieline CAD #	22620
Instructions: Follow 19-211 spec Stamp LOT and EXP on box			
<b>Factory Proofs / Samples</b>			
Proof Type	Yes	Attn:	
Printer Digital Output	Email	Carrie Booton	cbooton@veridianhealthcare.com
Notes: Send when available			
Color Proofs	Email	Carrie Booton	cbooton@veridianhealthcare.com
Notes: Photoproofed sample next to Pantone swatch for comparison			
Pre-Production Samples	International Express Shipping	Attn: Carrie Booton	Veridian Healthcare 1175 Lakeside Drive Gurnee, IL 60031 USA 866-736-3300
Requesting 3 printed packaging samples			
Notes: Send pre-production samples and provide tracking information.			
Post-Production Samples	International Express Shipping	Attn: Carrie Booton	Veridian Healthcare 1175 Lakeside Drive Gurnee, IL 60031 USA 866-736-3300
Requesting 3 complete product packaging samples of each model			
Notes: OK to ship with other samples to save on shipping costs. Please provide tracking information on samples ship.			

CAD# 22620  
 REF: 1 & 1.25oz Ointment  
 0.016 SBS  
 2/4/2021

PRINT SIDE



		Veridian Healthcare, LLC 1175 Lakeside Drive Gurnee, IL 60031	
<b>Product Artwork Specs</b>			
Author / Artwork Release	C.Booton	04-16-2021	
<b>Packaging Artwork</b>			
VH Model No. / UPC	19-211	8-45717-01008-5	
Brand / Product Name	TheraCare	Hydrocortisone Cream, 1oz	
Digital File Name	#92-19019.0421.TUBE hydrocortisone cream		
Native File Type / Format	Illustrator CSS	EPS	
Supplier / Model No.	ALKA	-	
PO No. / Date	-	-	
<b>Packaging / Printing / Packing</b>			
Packaging Type	Tube, Multi-Packing	Ink Type	UV Ink
Flat Size	103.0mm	Process Colors	CMYK
	78.5mm (25 Dia)	Pantone Colors	PMS RED 032C
Material	HDPE	Pantone Colors	PMS 7627C
Material Color	White	Gloss Coating	UV Coating
Post-Consumer Resin	if possible	No. Sides Printed	1 Side
Cap Style	Standard, White	Dieline CAD#	Factory
			
Instructions: Follow 19211 Specs Crimp LOT and BXP on tube end.			
<b>Factory Proofs / Samples</b>			
Proof Type	Via	Att'n:	
Printer Digital Output	Email	Carrie Booton cbooton@veridianhealthcare.com	
Notes: Send when available			
Color Proofs	Email	Carrie Booton cbooton@veridianhealthcare.com	
Notes: Photo of printed sample next to Pantone swatch for comparison			
Pre-Production Samples	International Express Shipping	Att'n: Carrie Booton Veridian Healthcare 1175 Lakeside Drive Gurnee, IL 60031 USA 866-736-3330	
Notes: Send pre-production samples and provide tracking information.			
Post-Production Samples	International Express Shipping	Att'n: Carrie Booton Veridian Healthcare 1175 Lakeside Drive Gurnee, IL 60031 USA 866-736-3330	
Notes: OK to ship with other samples to save on shipping costs. Please provide tracking number when samples ship.			

19-211 Hydrocortisone Cream, 1oz

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**

**HYDROCORTISONE** (UNII: W4X0X7BPJ) (HYDROCORTISONE - UNII:W4X0X7BPJ) **HYDROCORTISONE** 10 mg in 1 g

### Inactive Ingredients

Ingredient Name	Strength
<b>SORBITAN MONOSTEARATE</b> (UNII: NVZ4I0H58X)	
<b>CETOSTEARYL ALCOHOL</b> (UNII: 2DMT128M1S)	
<b>GLYCERYL MONOSTEARATE</b> (UNII: 230OU9XXE4)	
<b>METHYLPARABEN</b> (UNII: A2I8C7HI9T)	
<b>MINERAL OIL</b> (UNII: T5L8T28FGP)	
<b>PETROLATUM</b> (UNII: 4T6H12BN9U)	
<b>PROPYLPARABEN</b> (UNII: Z8IX2SC1OH)	
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>EDETATE SODIUM</b> (UNII: MP1J8420LU)	
<b>POLYSORBATE 60</b> (UNII: CAL22UVI4M)	
<b>PROPYLENE GLYCOL</b> (UNII: 6DC9Q167V3)	

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:71101-211-01	1 in 1 CARTON	05/01/2021	
1		28.3 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	05/01/2021	

**Labeler** - Veridian Healthcare (830437997)

### Establishment

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

Revised: 5/2021

Veridian Healthcare