

**THERACARE EXTRA STRENGTH ANTI-ITCH CREAM ITCH STOPPING-  
diphenhydramine hydrochloride and zinc acetate 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 Extra Strength Anti-Itch Cream**

**Drug Facts**

<b>Active ingredients</b>	<b>Purpose</b>
Diphenhydramine hydrochloride 2%	Topical analgesic
Zinc acetate 0.1%	Skin protectant

**Uses**

- temporarily relieves pain and itching associated with:
  - insect bites
  - minor burns
  - sunburn
  - minor skin irritations
  - minor cuts
  - scrapes
  - minor skin irritations
  - rashes due to poison ivy, poison oak, oak, and sumac
- dries the oozing and weeping of poison ivy, poison oak, and poison sumac

**Warnings**

For external use only

Do not use

- **on large areas of the body**
- **with any other product containing diphenhydramine, even one taken by mouth**

Ask a doctor before use

- **on chicken pox**
- **on measles**

When using this product

- **use only as directed**
- **avoid contact with eyes**

Stop use and ask a doctor if

- **condition worsens or does not improve within 7 days**

- **symptoms persist for more than 7 days or clear up and occur again within a few days**

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

### **Directions**

- **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**

### **Other information**

- **store at 20°C-25°C (68°C/77°F)**
- **do not use if tube seal under cap is broken**

### **Inactive ingredients**

cetyl alcohol, di sodium edetate, Diazolidinyl urea, methylparaben, peg-100 stearate, peg-2 stearate, petrolatum, potassium hydroxide, polyethylene glycol, propylparaben, stearic acid, water

### **Questions?**

















toll-free 866-326-1313

### **TheraCare Extra Strength Anti-Itch Cream**

		Veridian Healthcare, LLC 1175 Lakeside Drive Gurnee, IL 60031	
<b>Product Artwork Specs</b>			
Author / Artwork Release	C. Borton	03-26-2021	
<b>Packaging Artwork</b>			
VH Model No. / UPC	19-215	8-45717-01012-2	
Brand / Product Name	TheraCare	anti-itch cream 1.25oz	
Digital File Name	192-19026-0921 PNG anti-itch cream		
Native File Type / Format	Illustrator CS5	EPS	
Supplier / Model No.	ALBA	-	
PO No. / Date	-	-	
<b>Packaging / Printing / Packing</b>			
Packaging Type	Folded hanging box	Link Type	Standard
Flat Size	8.125" W	Process Colors	CMYK
	9.0312 H	Pantone Colors	PMS 286C
Stock	016 SBS	Pantone Colors	--
Diecut	Yes	Coating	Gloss Aqueous
Recycled Content	20% post-consumer	No. Sides Printed	1 Side
Bindery	Score, Fold & Glue	Dieline CAD #	22620
Instructions: Follow 19215 specs Print LO Tand EXP on box			
<b>Factory Proofs / Samples</b>			
Proof Type	Via	Attn:	
Printer	Digital Output	Email	Carrie.Borton@veridianhealthcare.com
Notes: Send when available			
Color Proofs	Email	Carrie.Borton	cborton@veridianhealthcare.com
Notes: Photo of printed sample next to Pantone swatch for comparison			
Pre-Production Samples	International Express Shipping	Attn: Carrie Borton 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	Attn: Carrie Borton Veridian Healthcare 1175 Lakeside Drive Gurnee, IL 60031 USA 866-736-3330	
Notes: OK to N with other samples to save on shipping costs. Please provide tracking number when sample is by.			

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

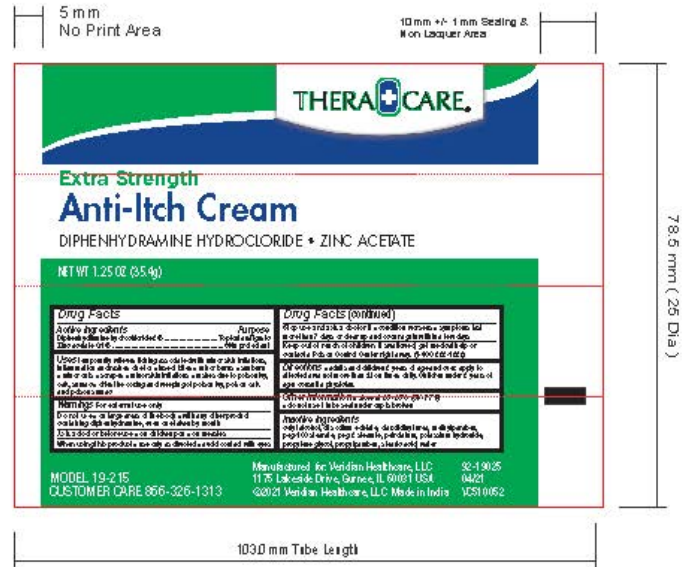
PRINT SIDE

		Veridian Healthcare, LLC 1175 Lakeside Drive Gurnee, IL 60031											
<b>Product Artwork Specs</b>													
Author / Artwork Release	C. Booton	04-16-2021											
Packaging Artwork													
VH Model No. / UPC	19-215	8-46717-01012-2											
Brand / Product Name	The raCare	Anti-Itch Cream, 1.25oz											
Digital File Name	#52-19025 0421 TUBE anti-itch.cream												
Native File Type / Format	Illustrator CS5	EPS											
Supplier / Model No.	ALKA	-											
PO No. / Date	-	-											
Packaging / Printing / Packing													
Packaging Type	Tube Makita Packaging	Ink Type	UV Ink										
Flat Size	103.0mm	Process Colors	CMYK										
	78.5mm (25 Dia)	Pantone Colors	PMS 286C										
Material	HDPE	Pantone Colors	...										
Material Color	White	Gloss Coating	UV Coating										
Post-Consumer Resin	if possible	No. Sides Printed	1 Side										
Cap Style	Standard White	Die Line CAD #	Factory										
<table border="1"> <tr> <td></td> <td></td> <td></td> <td></td> <td></td> </tr> <tr> <td>Cyan</td> <td>Magenta</td> <td>Yellow</td> <td>Black</td> <td>PMS 286C</td> </tr> </table>									Cyan	Magenta	Yellow	Black	PMS 286C
													
Cyan	Magenta	Yellow	Black	PMS 286C									
Instructions: Follow 19-215 Specs Crimp LOT and EXP on tube end.													
Factory Proofs / Samples													
Proof Type	Via	Attn:											
Printer Digital Output	Email	Carrie Booton cbooton@veridianhealthcare											
Notes: Send when available													
Color Proofs	Email	Carrie Booton cbooton@veridianhealthcare											
Notes: Photo of printed 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 866-736-3330											
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 866-736-3330											
Notes: OK to ship with other samples to save on shipping costs. Please provide tracking number when samples ship.													

19-215 Anti-Itch Cream, 1.25oz

TUBE DIELINE

Scale: 100% (do not adjust)



## THERACARE EXTRA STRENGTH ANTI-ITCH CREAM ITCH STOPPING

diphenhydramine hydrochloride and zinc acetate cream

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:71101-215
<b>Route of Administration</b>	TOPICAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>DIPHENHYDRAMINE HYDROCHLORIDE</b> (UNII: TC2D6JAD40) (DIPHENHYDRAMINE - UNII:8GTS82S83M)	DIPHENHYDRAMINE HYDROCHLORIDE	20 mg in 1 g
<b>ZINC ACETATE</b> (UNII: FM5526K07A) (ZINC CATION - UNII:13S1S8SF37)	ZINC ACETATE	1 mg in 1 g

### Inactive Ingredients

Ingredient Name	Strength
<b>EDETATE SODIUM</b> (UNII: MP1J8420LU)	
<b>PEG-2 STEARATE</b> (UNII: 94YQ11Y95F)	
<b>STEARIC ACID</b> (UNII: 4ELV7Z65AP)	
<b>PETROLATUM</b> (UNII: 4T6H12BN9U)	
<b>POLYOXYL 100 STEARATE</b> (UNII: YD01N1999R)	
<b>POTASSIUM HYDROXIDE</b> (UNII: WZH3C48M4T)	
<b>CETYL ALCOHOL</b> (UNII: 936JST6JCN)	
<b>DIAZOLIDINYL UREA</b> (UNII: H5RIZ3MPW4)	
<b>METHYLPARABEN</b> (UNII: A2I8C7HI9T)	
<b>PROPYLENE GLYCOL</b> (UNII: 6DC9Q167V3)	
<b>PROPYLPARABEN</b> (UNII: Z8IX2SC1OH)	
<b>WATER</b> (UNII: 059QF0KO0R)	

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:71101-215-01	1 in 1 CARTON	09/01/2021	
1		35.4 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	09/01/2021	

**Labeler** - Veridian Healthcare (830437997)

### Establishment

Name	Address	ID/FEI	Business Operations
ANICARE PHARMACEUTICALS PRIVATE LIMITED		916837425	manufacture(71101-215)