TRICALM HYDROGEL- aluminum acetate gel Modular Thermal Technologies LLC Dba Life Wear Technologies

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.

TriCalm[®] Hydrogel

Drug Facts

Active ingredient

Aluminum acetate (0.2%)

Purpose

Astringent

Uses

For temporary relief of minor skin irritations due to:

- poison ivy
- poison oak
- poison sumac
- insect bites
- athlete's foot
- rashes caused by soaps, detergents, cosmetics or jewelry

Warnings

For external use only.

When using this product

- Avoid contact with eyes. If contact occurs, rinse thoroughly with water.
- Do not apply to open wounds.

Stop use and ask a doctor if

• condition worsens or symptoms last for more than 7 days.

Keep out of reach of children.

• If swallowed, get medical help or contact a Poison Control Center right away.

Directions

- Adults and children two years of age and older, apply to affected area as needed or as directed by a physician.
- Consult a physician for children under the age of two.

Inactive ingredients

Butylene glycol, caprylyl glycol, dehydroacetic acid, ethylhexylglycerin, glycine, hexylene glycol, malic acid, phenoxyethanol, purified water, strontium chloride hexahydrate, xanthan gum.

Questions?

Call 855-TRI-CALM

PRINCIPAL DISPLAY PANEL - 60 mL Vertical Carton

 $TRICALM^{\circledR}$

Rapid Relief

From Itching,

Burning

& Stinging

SOOTHING

ITCH RELIEF

HYDROGEL

Steroid-Free

Aluminum Acetate Astringent

2 FL OZ (60mL)



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LEARN ABOUT TRICALM'S ITCH FREE GUARANTEE AT TRICALM.COM/GUARANTEE OR BY CALLING 855-TRI-CALM

Manufactured for Life Wear Technologies, LLC 505 Rope Willems Viss, North Kingstown, IR CRIST 505 THE-CHUM Hosem-born US-Februs, SJ76-655, S364,203; 6,138,800, 7,404,957, 8,147,805



GUARANTEED ITCH RELIEF OR YOUR MONEY BACK

TRICALM

Rapid Relief From Itching, Burning & Stinging

SOOTHING ITCH RELIEF HYDROGEL

Steroid-Free **Aluminum Acetate Astringent**

2 FL OZ (60mL)

TRICALM'

FOR RELIEF OF:

Dry, itchy skin

Itchy rashes from soaps detergents cosmetics jewelry

Bug bites

Poison ivy, oak, sumac

Athlete's foot

tricalm.com

LOT

5433317

4 4

ITCH.BURN.STING.GONE.

FOR RELIEF OF:

TRICALM

NON-GREASY, ABSORBS QUICKLY

STEROID FREE

FAST ACTING

FORMULATED WITH

SOOTHING INGREDIENTS

PN66027.03



Principal Display Panel Tube

TRICALM Steroid-Free Hydrogel
For Itching Burning and Stinging
2.0 FLOZ (60mL)



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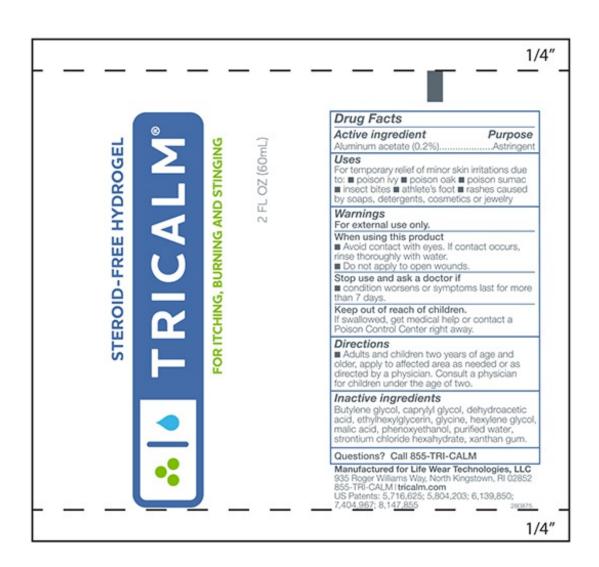
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Questions? Call 855-TRI-CALM

Manufactured for Life Wear Technologies, LLC 935 Roger Williams Way, North Kingstown, RI 02852 855-TRI-CALM | tricalm.com US Patents: 5,716,625; 5,804,203; 6,139,850; 7,404,967; 8,147,855

1/4"



TRICALM HYDROGEL

aluminum acetate gel

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:71207-100
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety Ingredient Name Basis of Strength ALUMINUM ACETATE (UNII: 80 EHD8 I43D) (ALUMINUM CATION - UNII:3XHB1D032B) ALUMINUM ACETATE 2 mg in 1 mL

Inactive Ingredients		
Ingredient Name	Strength	
BUTYLENE GLYCOL (UNII: 3XUS85K0RA)		
CAPRYLYL GLYCOL (UNII: 00 YIU5438 U)		
DEHYDRO ACETIC ACID (UNII: 2KAG279R6R)		
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)		
GLYCINE (UNII: TE7660 XO 1C)		
HEXYLENE GLYCOL (UNII: KEH0 A3F75J)		

MALIC ACID (UNII: 817L1N4CKP)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
WATER (UNII: 059QF0KO0R)	
STRONTIUM CHLORIDE HEXAHYDRATE (UNII: O09USB7Z44)	
XANTHAN GUM (UNII: TTV12P4NEE)	

P	Packaging			
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:71207-100-10	1 in 1 CARTON	11/0 2/20 16	
1		60 mL in 1 TUBE; Type 0: Not a Combination Product		
2	NDC:71207-100-20	1 in 1 CARTON	11/02/2016	
2		60 mL 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 FINAL	part347	11/0 1/20 13	

Labeler - Modular Thermal Technologies LLC Dba Life Wear Technologies (131710969)

Registrant - Sheffield Pharmaceuticals LLC (151177797)

Establishment				
Name	Address	ID/FEI	Business Operations	
Sheffield Pharmaceuticals LLC		151177797	manufacture(71207-100)	

Revised: 3/2017 Modular Thermal Technologies LLC Dba Life Wear Technologies