

ARCTIVA ECZEMA CREAM- eczema cream cream
Tropical. Enterprises International, Inc.

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.

Arctiva Eczema Cream

Active Ingredient

Colloidal oatmeal 1%.....

Purpose... Skin protectant

Uses: Temporarily protects and helps relieve minor skin irritations, redness, dryness, cracking and itching

due to eczema and dermatitis.

Warnings

For external use only. When using this product: do not get into eyes.

Stop using and ask a doctor if: condition worsen, symptoms last 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 immediately.

Directions Apply twice daily or as needed.
For best results apply after cleansing.

Inactive Ingredients: Water, Cetyl Alcohol, Stearyl Alcohol,

Candelilla/Jojoba/Rice Bran Polyglyceryl-3 esters, Glyceryl Stearate, Sodium Hydroxide, Sodium stearoyl lactylate, Cetearyl Alcohol, Phenoxyethanol, Pentylene Glycol,

Hydrosuf (Glycolipids), Glycolic Acid, Vitamin B3 (Niacinamide), Hydroxyethylcellulose, Ethylhexyglycerin,

Sodium Ascorbyl Phosphate, Vitamin A (Retinyl Palmitate), Tocopherol, Soybean Oil.

Other Information: Store at room temperature.

Questions: 1-833-933-SKIN (7546)

THE ARCTIVA GUARANTEE

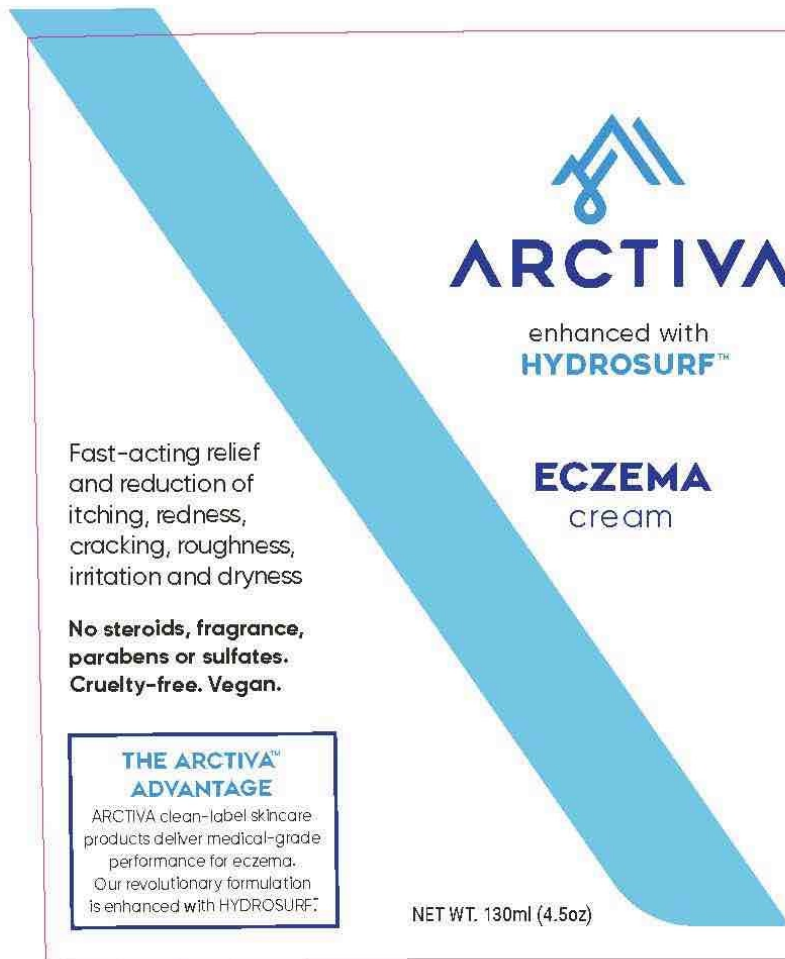
Arctiva relief goes beyond the surface. If for any reason you're not completely satisfied contact us within 60 days of your purchase for a full refund.


Distributed by:

Arctiva Wellness, LLC

30600 Aurora Rd.
Suite 180
Salon, OH 44139
Made in U.S.A
arctivaskin.com

130ml




ARCTIVA
enhanced with
HYDROSURF™
ECZEMA
cream

Fast-acting relief
and reduction of
itching, redness,
cracking, roughness,
irritation and dryness

**No steroids, fragrance,
parabens or sulfates.
Cruelty-free. Vegan.**

**THE ARCTIVA™
ADVANTAGE**
ARCTIVA clean-label skincare
products deliver medical-grade
performance for eczema.
Our revolutionary formulation
is enhanced with HYDROSURF.

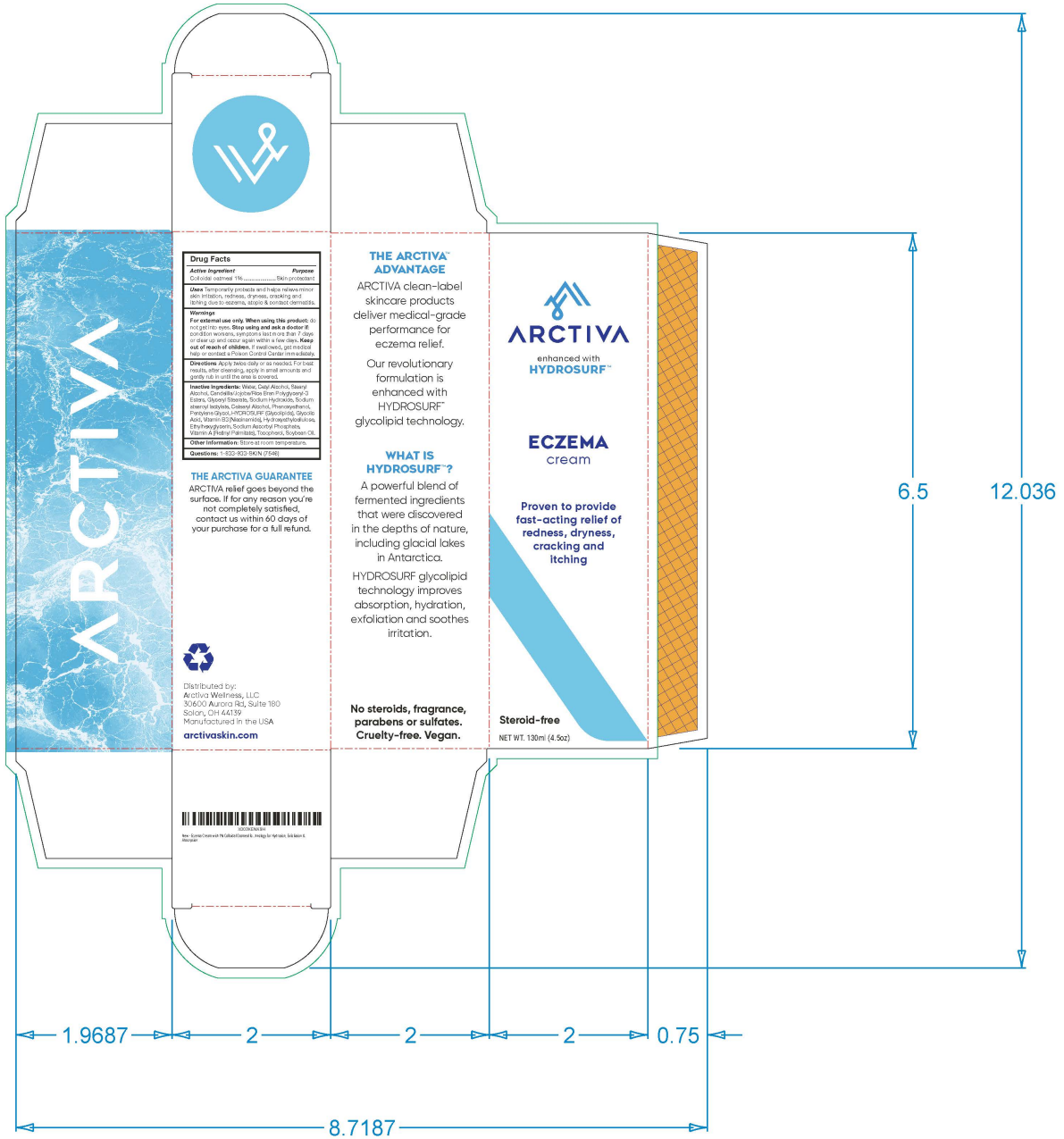
NET WT. 130ml (4.5oz)

Drug Facts	
Active Ingredient	Purpose
Colloidal oatmeal 1%	Skin protectant
Uses Temporarily protects and helps relieve minor skin irritation, redness, dryness, cracking and itching due to eczema, atopic & contact dermatitis.	
Warnings For external use only. When using this product: do not get into eyes. Stop using and ask a doctor if condition worsens. Symptoms last 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 immediately.	
Directions Apply twice daily or as needed. For best results, after cleansing, apply in small amounts and gently rub in until the area is covered.	
Inactive Ingredients: Water, Cetyl Alcohol, Stearyl Alcohol, Candellila/Jojoba/Rice Bran Polyglyceryl-3 Esters, Glyceryl Stearate, Sodium Hydroxide, Sodium stearoyl lactylate, Cetearyl Alcohol, Phenoxethanol, Pentylene Glycol, HYDROSURF (Glycolipids), Glycolic Acid, Vitamin B3 (Niacinamide), Hydroxyethylcellulose, Ethylhexylglycerin, Sodium Ascorbyl Phosphate, Vitamin A (Retinyl Palmitate), Tocopherol, Soybean Oil.	
Other Information: Store at room temperature.	
Questions: 1-800-930-SKIN (7546)	

THE ARCTIVA GUARANTEE
ARCTIVA relief goes beyond the surface. If for any reason you're not completely satisfied contact us within 60 days of your purchase for a full refund.

Distributed by:
Arctiva Wellness, LLC
30600 Aurora Rd,
Suite 180
Salon, OH 44139
Manufactured in the U.S.A.
arctivaskin.com

PMS Black Cerulean Sky Cobalt
 PMS 2925 PMS 305 PMS 2736



40ml

Arctiva Eczema Travel Size/Sample Label

Dieline

PMS 305

PMS 2925

PMS 2736

PMS Black

Proven to provide fast-acting relief of redness, dryness, cracking and itching.

No steroids, fragrance, parabens or sulfates. Cruelty-free. Vegan.

THE ARCTIVA GUARANTEE
ARCTIVA relief goes beyond the surface. If for any reason you're not completely satisfied contact us within 60 days of your purchase for a full refund.

THE ARCTIVA[®] ADVANTAGE
ARCTIVA clean-label skincare products deliver medical-grade performance for eczema. Our revolutionary formulation is enhanced with Hydrosurf[®].

Distributed by:
Arctiva Wellness, LLC
30000 Avenue Rd.
Suite 100
Solon, OH 44139
Manufactured in the USA
arctivawellness.com



enhanced with
HYDROSURF[®]

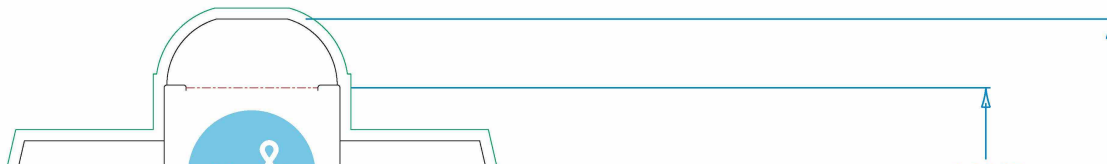
ECZEMA
cream

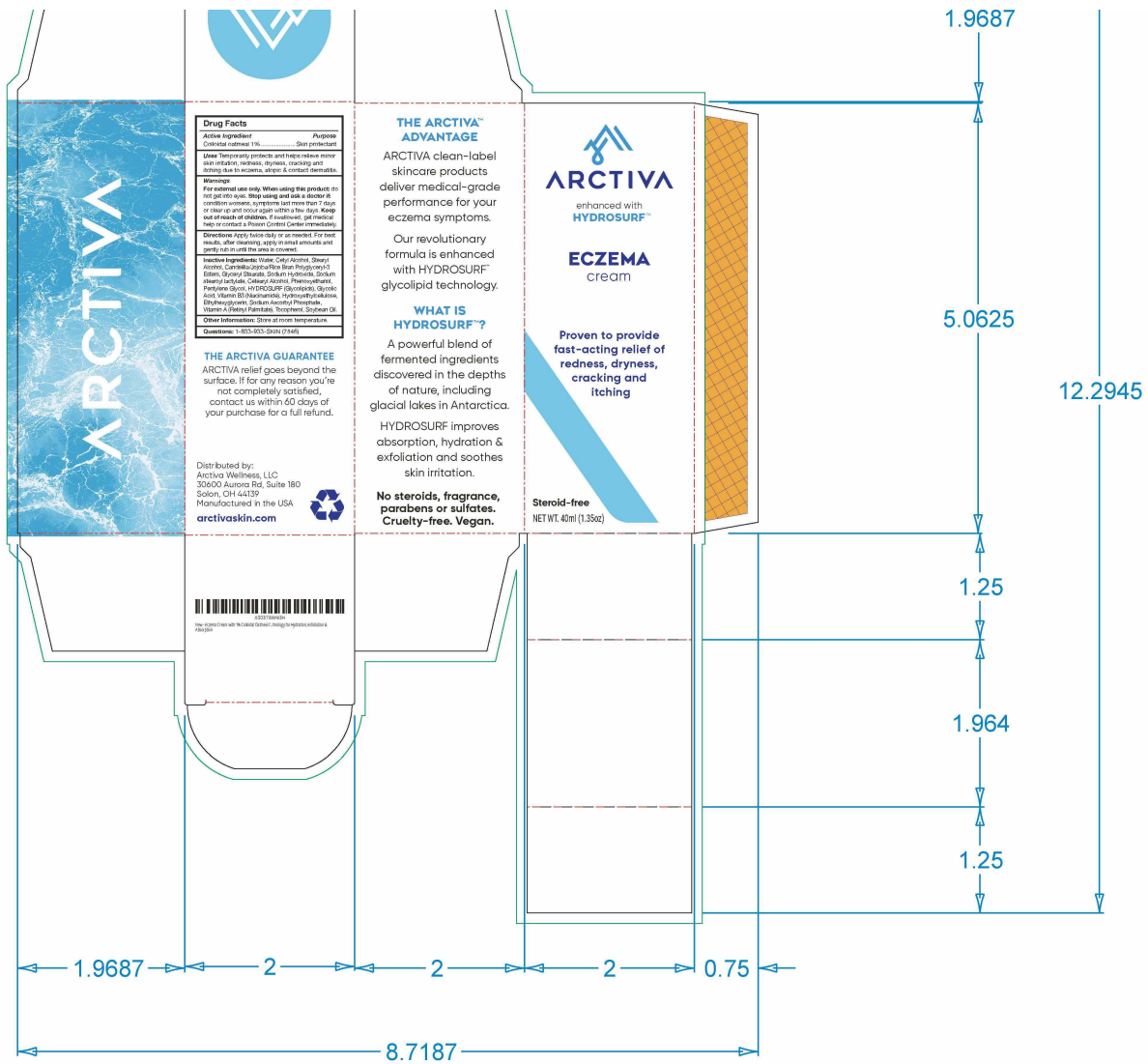
Drug Facts

Active Ingredient(s) Colloidal oatmeal 1%	Purpose(s) Skin protectant
Uses Temporarily protects and helps relieve minor skin irritation, redness, dryness, cracking and itching due to eczema, atopic & contact dermatitis.	
Warnings For external use only. When using this product, do not get into eyes. Wash using mild soap & water. If condition worsens, symptoms last more than 7 days or recur again within a few days, leave use of product off. If symptoms persist, get medical help or contact a Poison Control Center immediately.	
Directions Apply twice daily or as needed. For best results, after cleansing, apply to small amounts and gently rub to until the area is covered.	
Contains Ingredients: Water, Oat Alcohol, Glycerol Acrylate, Carbomer, Arctiva Plus from Polyglyceryl-4 Esters, Glyceryl Stearate, Sodium Hydroxide, Sodium Dimethyl Sulfate, Glycerol Alcohol, Phenoxyethanol, Polyethylene Glycol, Hydroxyethyl Cellulose, Carbonyl Amyl, Methyl Cellulose, Polymethylsilyoxane, Polymethylsiloxane, Ethylhexylglycerin, Sodium Acrylate, Phenoxyethanol, Methyl Methacrylate, Tocopherol, Sodium Oleate, Other Ingredients: Stearic Acid, Alcohol, Glycerol, Carbomer, Arctiva Plus from Polyglyceryl-4 Esters, Glyceryl Stearate, Sodium Hydroxide, Sodium Dimethyl Sulfate, Glycerol Alcohol, Phenoxyethanol, Polyethylene Glycol, Hydroxyethyl Cellulose, Carbonyl Amyl, Methyl Cellulose, Polymethylsilyoxane, Polymethylsiloxane, Ethylhexylglycerin, Sodium Acrylate, Phenoxyethanol, Methyl Methacrylate, Tocopherol, Sodium Oleate.	
Other Information: Store at room temperature.	
Questions: 1-855-622-SKIN (7546)	

Steroid-free
NET WT. 41ml (1.35oz)

PMS Black Cerulean PMS 2925 Sky PMS 305 Cobalt PMS 2736





ARCTIVA ECZEMA CREAM

eczema cream cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:58418-821
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
OATMEAL (UNII: 8PI54V663Y) (OATMEAL - UNII:8PI54V663Y)	OATMEAL	1 g in 130 mL

Inactive Ingredients

Ingredient Name	Strength
-----------------	----------

JOJOBA OIL, RANDOMIZED (UNII: 7F0EV20QYL)
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)
NIACINAMIDE (UNII: 25X518RD4)
HYDROXYETHYL CELLULOSE (280 MPA.S AT 2%) (UNII: 12VCE9HR9E)
SODIUM STEAROYL LACTYLATE (UNII: IN99IT31LN)
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)
RICE BRAN (UNII: R60QEP13IC)
POLYGLYCERIN-3 (UNII: 4A0NCJ6RD6)
WATER (UNII: 059QF0KO0R)
SODIUM HYDROXIDE (UNII: 55X04QC32I)
SODIUM ASCORBYL PHOSPHATE (UNII: 836SJG51DR)
CETYL ALCOHOL (UNII: 936JST6JCN)
STEARYL ALCOHOL (UNII: 2KR89I4H1Y)
VITAMIN A PALMITATE (UNII: 1D1K0N0VVC)
PHENOXYETHANOL (UNII: HIE492ZZ3T)
PENTYLENE GLYCOL (UNII: 50C1307PZG)
GLYCOLIC ACID (UNII: 0WT12SX38S)
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)
CANDELILLA WAX (UNII: WL0328HX19)
LIPID A 504 (UNII: Q2VF73396U)

Product Characteristics

Color	white (lotion)	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:58418-821-99	1 in 1 CARTON	02/01/2023	
1	NDC:58418-821-45	130 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product		
2	NDC:58418-821-44	1 in 1 CARTON	10/02/2023	
2	NDC:58418-821-40	40 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	M016	02/01/2023	

Labeler - Tropical. Enterprises International, Inc. (091986179)

