

**BLUE-EMU ULTRA WITH HEMP SEED- trolamine salicylate cream  
NFI, LLC**

*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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**Blue-Emu® Ultra with Hemp Seed Oil**

**Active ingredient**

Trolamine salicylate 10%

**Purpose**

Topical analgesic

**Uses**

temporarily relieves minor pain associated with:

- arthritis
- simple backache
- muscle strains
- sprains
- bruises
- cramps

**Warnings**

**For external use only**

**Allergy alert:** If prone to allergic reaction from aspirin or salicylates, consult a doctor before use.

**When using this product**

- use only as directed
- do not bandage tightly or use with a heating pad
- avoid contact with eyes or mucous membranes
- do not apply to wounds or damaged skin.

**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
- redness is present

- irritation develops.

**If pregnant or breast-feeding,** ask a health professional before use.

**Keep out of reach of children.** If swallowed, get medical help or contact a Poison Control Center right away.

## **Directions**

### **adults and children over 12 years of age:**

- apply generously to affected area
- massage into painful area until thoroughly absorbed into skin
- repeat as necessary, but no more than 4 times daily

**children 12 years or younger:** ask a doctor.

## **Other information**

Store at 68-77°F (20-25°C)

## **Inactive ingredients**

acrylates/c10-30 alkyl acrylate crosspolymer, allantoin, aloe barbadensis leaf juice (aloe vera), cannabis sativa seed oil, cetyl alcohol, dimethicone, disodium EDTA, emu oil, ethylhexylglycerin, FD & C Blue#1, glucosamine HCl, glycerin, glyceryl stearate and peg-100 stearate, methylsulfonylmethane, mineral oil, panthenol, phenoxyethanol, polysorbate 80, stearic acid, triethanolamine, tocopheryl acetate (Vitamin E), water.

DISTRIBUTED BY: **NFI CONSUMER PRODUCTS**

501 Fifth Street • Bristol, TN 37620 • 1-800-432-9334

**WWW.BLUE-EMU.COM**

## **PRINCIPAL DISPLAY PANEL - 88 g Tube Carton Label**

ULTRA

BLUE-EMU®

-HEMP-

CANNABIS SATIVA  
SEED OIL + EMU OIL

TOPICAL PAIN RELIEF CREAM  
NET WT 3 OZ. (88g)



**BLUE-EMU<sup>®</sup>**  
-HEMP-

PAIN RELIEF

**ULTRA**

**ULTRA**

CANNABIS SATIVA  
SEED OIL + EMU OIL

**BLUE-EMU<sup>®</sup>**  
-HEMP-

CANNABIS SATIVA  
SEED OIL + EMU OIL

**ULTRA**

CANNABIS SATIVA  
SEED OIL + EMU OIL

**Drug Facts**

Active Ingredient	Purpose
Trolamine salicylate 10%	Topical analgesic

**Uses** temporarily relieves minor pain associated with: ● arthritis ● simple backache ● muscle strains ● sprains ● bruises ● cramps

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**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 ● redness is present ● irritation develops.

**If pregnant or breast-feeding,** ask a health professional before use. **Keep out of reach of children.** If swallowed, get medical help or contact a Poison Control Center right away.

**Directions**

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**Other information** Store at 68-77°F (20-25°C)

**Inactive ingredients**

acrylates C10-30 alkyl acrylate copolymer, albutin, aloe barbadensis leaf juice (aloe vera), cannabis sativa seed oil, cetyl alcohol, dimethicone, disodium EDTA, emu oil, ethylhexylglycerin, FD & C Blue #1, glucosamine HCl, glycerin, glyceryl stearate and cop-100 stearyl, methylsulfonylmethane, mineral oil, panthenol, phenoxethanol, polyisobutyl 90, stearic acid, tetrahydroamine, toopherol acetate (Vitamin E), water

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v. 04142020

**BLUE-EMU<sup>®</sup>**  
-HEMP-

CANNABIS SATIVA  
SEED OIL + EMU OIL



TOPICAL PAIN RELIEF CREAM  
NET WT 3 OZ. (88g)

**BLUE-EMU ULTRA WITH HEMP SEED**

trolamine salicylate cream

## Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:69993-200
<b>Route of Administration</b>	TOPICAL		

## Active Ingredient/Active Moiety

<b>Ingredient Name</b>	<b>Basis of Strength</b>	<b>Strength</b>
<b>TROLAMINE SALICYLATE</b> (UNII: H8O4040BHD) (SALICYLIC ACID - UNII:O414PZ4LPZ)	TROLAMINE SALICYLATE	0.1 g in 1 g

## Inactive Ingredients

<b>Ingredient Name</b>	<b>Strength</b>
<b>ALLANTOIN</b> (UNII: 344S277G0Z)	
<b>ALOE VERA LEAF</b> (UNII: ZY81Z83H0X)	
<b>CANNABIS SATIVA SEED OIL</b> (UNII: 69VJ1LPN1S)	
<b>CETYL ALCOHOL</b> (UNII: 936JST6JCN)	
<b>DIMETHICONE</b> (UNII: 92RU3N3Y1O)	
<b>EDETATE DISODIUM ANHYDROUS</b> (UNII: 8NLQ36F6MM)	
<b>EMU OIL</b> (UNII: 344821WD61)	
<b>ETHYLHEXYLGLYCERIN</b> (UNII: 147D247K3P)	
<b>FD&amp;C BLUE NO. 1</b> (UNII: H3R47K3TBD)	
<b>GLUCOSAMINE HYDROCHLORIDE</b> (UNII: 750W5330FY)	
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	
<b>GLYCERYL STEARATE/PEG-100 STEARATE</b> (UNII: RD25J5V947)	
<b>DIMETHYL SULFONE</b> (UNII: 9H4PO4Z4FT)	
<b>MINERAL OIL</b> (UNII: T5L8T28FGP)	
<b>PANTHENOL</b> (UNII: WW9CM0O67Z)	
<b>PHENOXYETHANOL</b> (UNII: HIE492ZZ3T)	
<b>POLYSORBATE 80</b> (UNII: 6OZP39ZG8H)	
<b>STEARIC ACID</b> (UNII: 4ELV7Z65AP)	
<b>TROLAMINE</b> (UNII: 9O3K93S3TK)	
<b>.ALPHA.-TOCOPHEROL</b> (UNII: H4N855PNZ1)	
<b>WATER</b> (UNII: 059QF0KO0R)	

## Packaging

<b>#</b>	<b>Item Code</b>	<b>Package Description</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
1	NDC:69993-200-03	1 in 1 CARTON	04/05/2021	
1		88 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	04/05/2021	

**Labeler -** NFI, LLC (121681919)

### Establishment

Name	Address	ID/FEI	Business Operations
Gregory Pharmaceutical Holdings, Inc., dba UPM Pharmaceuticals		081301372	MANUFACTURE(69993-200)

Revised: 4/2023

NFI, LLC