# BLUE-EMU PAIN RELIEF MICRO-FOAM- trolamine salicylate aerosol, foam 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® Pain Relief Micro-Foam

## **Active Ingredients**

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.

## **Inactive Ingredients**

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

#### **DISTRIBUTED BY:**

#### **NFI CONSUMER PRODUCTS**

501 Fifth Street • Bristol, TN 37620

TOLL FREE: 1-800-432-9334

WWW.BLUE-EMU.COM

# PRINCIPAL DISPLAY PANEL - 99.2 g Canister Label

**SOFT & SOOTHING** 

BLUE-EMU®

Pain Relief

Micro-Foam™

**AMERICA'S** 

# 1

**ODOR** 

**FREE** 

EMU OIL FORMULA

Contains Emu Oil

NET WT 3.5 OZ (99.2g)



### **BLUE-EMU PAIN RELIEF MICRO-FOAM**

trolamine salicylate aerosol, foam

ı	Product Information
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Product Type HUMAN OTC DRUG Item Code (Source) NDC:69993-500

Route of Administration TOPICAL

# **Active Ingredient/Active Moiety**

Ingredient Name Basis of Strength Strength

**TROLAMINE SALICYLATE** (UNII: H8O4040BHD) (SALICYLIC ACID - TROLAMINE SALICYLATE 0.1 g in 1 g

Inactive Ingredients				
Ingredient Name	Strength			

CARBOMER INTERPOLYMER TYPE A (ALLYL SUCROSE CROSSLINKED) (UNII: 59TL3WG5CO) ALLANTOIN (UNII: 344S277G0Z)

ALOE VERA LEAF (UNII: ZY81Z83H0X)
CETYL ALCOHOL (UNII: 936JST6JCN)
GLUCOSAMINE (UNII: N08U5BOQ1K)

DIMETHICONE (UNII: 92RU3N3Y1O)	
EDETATE DISODIUM ANHYDROUS (UNII: 8NLQ36F6MM)	
PANTHENOL (UNII: WV9CM0O67Z)	
EMU OIL (UNII: 344821WD61)	
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
GLYCERIN (UNII: PDC6A3C0OX)	
GLYCERYL STEARATE/PEG-100 STEARATE (UNII: RD25J5V947)	
DIMETHYL SULFONE (UNII: 9H4PO4Z4FT)	
MINERAL OIL (UNII: T5L8T28FGP)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
POLYSORBATE 80 (UNII: 60ZP39ZG8H)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
TROLAMINE (UNII: 903K93S3TK)	
.ALPHATOCOPHEROL (UNII: H4N855PNZ1)	
WATER (UNII: 059QF0KO0R)	

l	Packaging				
	#	Item Code	Package Description	Marketing Start Date	Marketing End Date
	1	NDC:69993- 500-35	99.2 g in 1 CANISTER; Type 0: Not a Combination Product	04/05/2021	

Marketing In			
Marketing Application Number or Monograph Category Citation		Marketing Start Date	Marketing End Date
OTC monograph not final	part348	04/05/2021	

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

Establishment					
Name	Address	ID/FEI	<b>Business Operations</b>		
Formulated Solutions, LLC		143266687	MANUFACTURE(69993-500)		

Revised: 4/2023 NFI, LLC