

BLUE-EMU MAXIMUM PAIN RELIEF- 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.

Blue-Emu® Maximum Pain Relief

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.

Inactive ingredients

acrylates/c10-30 alkyl acrylate crosspolymer, allantoin, aloe barbadensis leaf juice (aloe vera), 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

TOLL FREE: 1-800-432-9334

WWW.BLUE-EMU.COM

PRINCIPAL DISPLAY PANEL - 88 g Tube Label

ARTHRITIS | MUSCLES | JOINTS

BLUE-EMU®

Fast Acting
Odor Free
+ Emu Oil

Maximum
Pain Relief

AMERICA'S

#1

EMU OIL FORMULA

ODOR

FREE

Contains Emu Oil

NET WT 3 OZ. (88g)

Drug Facts

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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.
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V.10252021

BLUE-EMU MAXIMUM PAIN RELIEF

trolamine salicylate cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:69993-300
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
TROLAMINE SALICYLATE (UNII: H8O4040BHD) (SALICYLIC ACID - UNII:O414PZ4LPZ)	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)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
EDETATE DISODIUM ANHYDROUS (UNII: 8NLQ36F6MM)	
EMU OIL (UNII: 344821WD61)	
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
GLUCOSAMINE HYDROCHLORIDE (UNII: 750W5330FY)	
GLYCERIN (UNII: PDC6A3C0OX)	
GLYCERYL STEARATE/PEG-100 STEARATE (UNII: RD25J5V947)	
DIMETHYL SULFONE (UNII: 9H4PO4Z4FT)	
MINERAL OIL (UNII: T5L8T28FGP)	
PANTHENOL (UNII: WW9CM0O67Z)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
TROLAMINE (UNII: 9O3K93S3TK)	
.ALPHA.-TOCOPHEROL (UNII: H4N855PNZ1)	
WATER (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69993-300-03	88 g in 1 TUBE; Type 0: Not a Combination Product	08/01/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	08/01/2020	

Labeler - NFI, LLC (121681919)

Establishment

Name	Address	ID/FEI	Business Operations
Gregory Pharmaceutical Holdings, Inc. dba UPM Pharmaceuticals		081301372	MANUFACTURE(69993-300)