

AVEDANA PAIN RELIEVING ROLL ON- menthol gel
Unipack 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.

Avedana® Pain Relief Roll-On

Active ingredients

Active ingredients	Purpose
Camphor 0.4%.....	Counter-Irritant
Natural Menthol USP 3.5%.....	Topical Analgesic

Purpose

Active ingredients	Purpose
Camphor 0.4%.....	Counter-Irritant
Natural Menthol USP 3.5%.....	Topical Analgesic

Uses

Soothing temporary relief from minor aches and pains associated with sore muscles, strains, joint discomfort, arthritis and tendinitis.

Warnings

For external use only.

Flammable

Keep away from excessive heat or open flames.

Ask a doctor before using if you

Ask a doctor before using if you: have sensitive skin, are pregnant or are breast feeding.

When using this product:

When using this product:

- Avoid contact with eyes and mucous membranes.
- Do not apply to wounds, damaged or irritated skin, or if excessive irritation develops.
- Do not bandage or use with a heating pad or device, ointments, creams, sprays or liniments.

- Wash hands with cool water after using.

Stop use and ask a doctor if:

Stop use and ask a doctor if: condition worsens, symptoms persist more than 7 days, or clear up and reoccur.

Keep out of reach of children:

Keep out of reach of children: If ingested, seek medical help and contact poison control center immediately.

Directions

- Adults/Children 2 years and older: Roll on the affected area up to 4 times daily.
- Children under 2 years of age: Consult a physician.

Inactive Ingredients:

Inactive Ingredients: Amino Methyl Propanol, Arnica montana, Boswellia serrata Extract, Carbomer, FD&C Blue #1, Glycerin USP, Ilex paraguariensis Extract, Isopropyl Alcohol USP, Propylene Glycol USP, Methyl Paraben, Purified Water, Zeodent

Directions

- Adults/Children 2 years and older: Roll on the affected area up to 4 times daily.
- Children under 2 years of age: Consult a physician.

Product Label

Avedana® Pain Relief Roll-On | 3 fl oz. | Bottle with Applicator.

- *Easy to Use and Apply.*
- *Fast Relief from Pain.*
- *Back on Run like never before.*

**SOOTHING
BOTANICAL
EXTRACTS**

Avedana®
...means no pain!

**PAIN RELIEVING
ROLL ON**

- ALL NATURAL
- NO SIDE EFFECTS
- NO RUBBING
- WON'T STAIN CLOTHING

Contains

- Natural Menthol
- Camphor
- Arnica • Ilex
- Boswellia

3 FL. OZ. (89 mL)



Manufactured By:
Unipack, Inc.
Pittsburgh, PA 15239.
info@unipackinc.com
(724)733-7381
Made in USA

NDC 43749 310 03



7 51393 00602 4

Lot:
Exp:

Drug Facts	
Active ingredients	
Camphor 0.4%.....
Natural Menthol USP 3.5%.....
Uses: Soothing temporary relief from pain associated with sore muscles, strains, joint pain, and tendinitis.	
Warnings: For external use only. Flammable: Keep away from excess heat and flame.	
Ask a doctor before using if you: have a history of asthma, are pregnant or are breast feeding.	
When using this product:	
• Avoid contact with eyes and mucous membranes. • Do not apply to wounds, damaged or irritated skin, or where excessive irritation develops. • Do not use with a heating pad or device, ointments, cream, or other topical products. • Wash hands with cool water after use.	
Stop use and ask a doctor if: condition persists more than 7 days, or clear up and then returns.	
Keep out of reach of children: If ingested, contact poison control center immediately.	
Directions	
• Adults/Children 2 years and older: Apply up to 4 times daily. • Children under 2 years of age: Consult your doctor.	
Inactive Ingredients: Amino Methyl Pantoic Acid, Boswellia serrata Extract, Carbomer, FD&C Yellow No. 6, Ilex paraguariensis Extract, Isopropyl Alcohol USP, Methyl Paraben, Purified Water.	

AVEDANA PAIN RELIEVING ROLL ON

menthol gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:43749-310
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	350 mg in 1 mL
CAMPHOR (SYNTHETIC) (UNII: 5TJD82A1ET) (CAMPHOR (SYNTHETIC) - UNII:5TJD82A1ET)	CAMPHOR (SYNTHETIC)	40 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	

CARBOMER 940 (UNII: 4Q93RCW27E)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
ISOPROPYL ALCOHOL (UNII: ND2M416302)	
BOSWELLIA SERRATA RESIN OIL (UNII: 5T1XCE6K8K)	
ILEX PARAGUARIENSIS LEAF (UNII: 1Q953B4O4F)	
ARNICA MONTANA (UNII: O80TY208ZW)	
GLYCERIN (UNII: PDC6A3C0OX)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
AMINOMETHYLPROPANOL (UNII: LU49E6626Q)	

Product Characteristics

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

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:43749-310-03	89 mL in 1 BOTTLE, WITH APPLICATOR; Type 0: Not a Combination Product	09/17/2017	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	09/29/2014	

Labeler - Unipack LLC (009248480)

Registrant - Unipack LLC (116015769)

Establishment

Name	Address	ID/FEI	Business Operations
Unipack LLC		009248480	manufacture(43749-310)