

**ART OF SPORT PAIN RELIEVING ULTRA STRENGTH- menthol, methyl salicylate cream
AOS GROUP INC., THE**

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.

ART OF SPORT PAIN RELIEVING CREAM ULTRA STRENGTH 3 OZ

ACTIVE INGREDIENTS

MENTHOL - 10%

METHYL SALICYLATE - 30%

PURPOSE

TOPICAL ANALGESIC

USES

TEMPORARILY RELIEVES THE MINOR ACHES AND PAINS OF MUSCLES AND JOINTS ASSOCIATED WITH:

- SIMPLE BACKACHE
- ARTHRITIS
- STRAINS
- BRUISES
- SPRAINS

WARNINGS

For external use only

Do not use:

- on wounds or damaged skin
- with a heating pad
- on a child under 12 years of age unless directed by a doctor

Ask a doctor before use if you have skin irritation or redness

When using this product:

- do not bandage tightly
- avoid contact with eyes or mucous membranes

Stop use and ask a doctor if:

- excessive skin irritation occurs
- condition worsens or symptoms persist for more than 7 days
- symptoms clear up and occur again within a few days

Keep out of reach of children to avoid accidental ingestion. If swallowed, get medical help or contact a Poison Control Center immediately.

DIRECTIONS

- use only as directed

- adults and children 12 years of age and older: apply to affected area not more than 3 to 4 times daily
- children under 12 years of age: ask a doctor

INACTIVE INGREDIENTS

ACRYLATES/C10-30 ALKYL ACRYLATE CROSSPOLYMER, ALOE BARBADENSIS LEAF JUICE, ARNICA MONTANA FLOWER EXTRACT, BUTYLENE GLYCOL, CAPRYLIC/CAPRIC TRIGLYCERIDE, CAPRYLYL GLYCOL, CETEARETH-20, CETEARYL ALCOHOL, DIMETHICONE, ETHYLHEXYLGLYCERIN, EUCALYPTUS GLOBULUS LEAF OIL, EUGENIA CARYOPHYLLUS (CLOVE) LEAF OIL, GLYCERIN, GLYCERYL STEARATE, HEXYLENE GLYCOL, HYDROXYETHYL ACRYLATE/SODIUM ACRYLOYLDIMETHYL TAURATE COPOLYMER, PEG-100 STEARATE, PHENOXYETHANOL, POLYSORBATE 60, PRUNUS AMYGDALUS DULCIS (SWEET ALMOND) OIL, SORBITAN ISOSTEARATE, SQUALANE, STEARIC ACID, TETRASODIUM GLUTAMATE DIACETATE, WATER, XANTHAN GUM

QUESTIONS?

Call 1-503-610-4055 help@artofsport.com

5,0 mm
UNVARNISHED AREA

OPEN END

BACK PANEL

FRONT PANEL

3,

Drug Facts

Active Ingredients	Purpose
Menthol 10%	Topical analgesic
Methyl Salicylate 30%	Topical analgesic

Uses temporarily relieves the minor aches and pains of muscles and joints associated with:

- simple backache
- arthritis
- strains
- bruises
- sprains

Warnings
For external use only

Do not use

- on wounds or damaged skin
- with a heating pad
- on a child under 12 years of age unless directed by a doctor

Ask a doctor before use if you have skin irritation or redness

When using this product

- do not bandage tightly
- avoid contact with eyes or mucous membranes

Stop use and ask a doctor if

- excessive skin irritation occurs
- condition worsens or symptoms persist for more than 7 days
- symptoms clear up and occur again within a few days

Keep out of reach of children to avoid accidental ingestion. If swallowed, get medical help or contact a Poison Control Center immediately.

Directions

- use only as directed
- adults and children 12 years of age and older: apply to affected area not more than 3 to 4 times daily
- children under 12 years of age: ask a doctor

Inactive Ingredients
Acrylates/C10-30 Alkyl Acrylate Copolymer, Aloe Barbadensis Leaf Juice, Arnica Montana Flower Extract, Butylene Glycol, Caprylic/Capric Triglyceride, Caprylyl Glycol, Ceteareth-20, Cetearyl Alcohol, Dimethicone, Ethylhexylglycerin, Eucalyptus Globulus Leaf Oil, Eugenia Caryophyllus (Clove) Leaf Oil, Glycerin, Glyceryl Stearate, Hexylene Glycol, Hydroxyethyl Acrylate/Sodium Acryloyldimethyl Taurate Copolymer, PEG-100 Stearate, Phenoxyethanol, Polysorbate 60, Prunus Amygdalus Dulcis (Sweet Almond) Oil, Sorbitan Isostearate, Squalane, Stearic Acid, Tetrasodium Glutamate Diacetate, Water, Xanthan Gum

Questions? Call 1-503-610-4055 help@artofsport.com

Dist. by THE ADS GROUP INC.
Los Angeles, CA 90025
ArtofSport.com

WITH OVERLAP

113,0 mm

ULDER

AOS
ART OF SPORT™

PAIN RELIEVING CREAM
ULTRA STRENGTH

RECOVERY CREAM

+ WORKS QUICKLY
+ RELIEVES SORE MUSCLES

Non-Greasy, Botanical Rich
With Arnica + Eucalyptus

NET WT. 3 OZ / 89 mL

8 55502 00809 8

6

Increased size 115%

PRINTED TO SHOULDER

ART OF SPORT PAIN RELIEVING ULTRA STRENGTH

menthol, methyl salicylate cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:72698-201
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	10 g in 100 mL
METHYL SALICYLATE (UNII: LAV5U5022Y) (SALICYLIC ACID - UNII:O414PZ4LPZ)	METHYL SALICYLATE	30 g in 100 mL

Inactive Ingredients

Ingredient Name	Strength
CARBOMER COPOLYMER TYPE A (ALLYL PENTAERYTHRITOL CROSSLINKED) (UNII: 71DD5V995L)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
ARNICA MONTANA FLOWER (UNII: OZ0E5Y15PZ)	
BUTYLENE GLYCOL (UNII: 3XUS85K0RA)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
POLYOXYL 20 CETOSTEARYL ETHER (UNII: YRC528SWUY)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	
EUCALYPTUS GLOBULUS LEAF (UNII: S546YLW6E6)	
CLOVE LEAF OIL (UNII: VCA5491KVF)	
GLYCERIN (UNII: PDC6A3C0OX)	
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	
HEXYLENE GLYCOL (UNII: KEH0A3F75J)	
HYDROXYETHYL ACRYLATE/SODIUM ACRYLOYLDIMETHYL TAURATE COPOLYMER (100000 MPAS AT 1.5%) (UNII: 86FQE96TZ4)	
PEG-100 STEARATE (UNII: YD01N1999R)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
POLYSORBATE 60 (UNII: CAL22UVI4M)	
ALMOND OIL (UNII: 66YXD4DKO9)	
SORBITAN ISOSTEARATE (UNII: 01S2G2C1E4)	
SQUALANE (UNII: GW89575KF9)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
TETRASODIUM GLUTAMATE DIACETATE (UNII: 5EHL50I4MY)	
WATER (UNII: 059QF0KO0R)	
XANTHAN GUM (UNII: TTV12P4NEE)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:72698-201-11	89 mL in 1 TUBE; Type 0: Not a Combination Product	01/08/2019	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	01/08/2019	

Labeler - AOS GROUP INC., THE (093257738)

Establishment

Name	Address	ID/FEI	Business Operations
Health Specialty		794053863	manufacture(72698-201)

Revised: 1/2019

AOS GROUP INC., THE