

**OARS AND ALPS MUSCLE RECOVERY BALM- menthol, methyl salicylate cream
Cosco International, Inc**

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.

OARS + ALPS MUSCLE RECOVERY BALM

DRUG FACTS

Menthol - 5%.....External Analgesic
Methyl Salicylate (NSAID) - 10%.....External Analgesic

Uses:

For temporary relief of minor aches and pains of muscles and joints associated with backache, muscle ache, strains, sprains, bruises, cramps, arthritis, and inflammation

Warnings:

For external use only.

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

Do not use on wounds or damaged skin, with a heating pad, on a child under 12 years of age with arthritis-like condition.

Ask a doctor before use if you have redness over the affected area.

If pregnant or breast-feeding, or if you have sensitive skin, ask your doctor before use

Avoid contact with eyes. If contact occurs, flush thoroughly with water.

When using this product avoid contact with eyes or mucous membranes, do not bandage tightly

Stop use and ask a doctor if: condition worsens or symptoms persist for more than 7 days, symptoms clear up and occur again within a few days, excessive skin irritation occurs

Directions:

Use only as directed. Apply generously and massage to affected area as needed. Do not use more than 3 to 4 times per day.

Children under 12 years of age: ask a doctor before use.

Inactive Ingredients:

Alpha-Tocopherol Acetate (Vitamin E), Aminomethylpropanol, Arnica Montana Flower, Carbomer, Cetostearyl Alcohol, Dimethyl Sulfone, Dimethyl Sulfoxide, Ethylhexylglycerin, Octyl Palmitate, Fragrance, Glucosamine, Glyceryl Monostearate, Magnesium Hydroxide, Phenoxyethanol, Polysorbate 80, Turmeric Oil, Water

Other Information:

Store at room temperature 68°F to 77°F (20° to 25°C)
Do not expose to excessive heat

Questions or comments?

Contact Hi@oarsandalps.com

Allergy Alert:

Do not use if you are allergic to salicylates (including aspirin) without consulting a physician.



MUSCLE RECOVERY BALM

Clinical Strength Formula

5% MENTHOL + 10% METHYL SALICYLATE



NATURALLY DERIVED INGREDIENTS

ARNICA + TURMERIC + VITAMIN E

FREE OF PARABENS,
PHTHALATES, SULFATES

3 Oz / 85 g

Drug Facts

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Menthol 5%	External Analgesic
Methyl Salicylate (NSAID) 10.0%	External Analgesic

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OARSANDALPS.COM
#TAKETOTHEOARS
Manufactured for
Oars + Alps LLC
Chicago, IL 60661
Made in USA

OARS AND ALPS MUSCLE RECOVERY BALM

menthol, methyl salicylate cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:52261-6300
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	0.05 kg in 1 kg

METHYL SALICYLATE (UNII: LAV5U5022Y) (SALICYLIC ACID - UNII:O414PZ4LPZ)

METHYL SALICYLATE

0.1 kg in 1 kg

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
CARBOMER HOMOPOLYMER TYPE C (UNII: 4Q93RCW27E)	
DIMETHYL SULFONE (UNII: 9H4PO4Z4FT)	
DIMETHYL SULFOXIDE (UNII: YOW8V9698H)	
N-ACETYLGLUCOSAMINE (UNII: V956696549)	
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	
Polysorbate 80 (UNII: 6OZP39ZG8H)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	
ARNICA MONTANA (UNII: O80TY208ZW)	
.ALPHA.-TOCOPHEROL ACETATE, DL- (UNII: WR1WPI7EW8)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	
MAGNESIUM HYDROXIDE (UNII: NBZ3QY004S)	
AMINOMETHYLPROPANOL (UNII: LU49E6626Q)	
TURMERIC OIL (UNII: 6KGS8SP16U)	
OCTYL PALMITATE (UNII: UYY8LE6Q5Y)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:52261-6300-1	0.085 kg in 1 TUBE; Type 0: Not a Combination Product	02/14/2022	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	02/14/2022	

Labeler - Cosco International, Inc (016433141)

Registrant - Cosco International, Inc (016433141)

Establishment

Name	Address	ID/FEI	Business Operations
Cosco International, Inc		016433141	manufacture(52261-6300) , label(52261-6300) , pack(52261-6300)