

ASystem Radical Relief Gel Roll-On- menthol, methyl salicylate gel
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.

ASystem Radical Relief Gel Roll-On

DRUG FACTS

Menthol - 10% (External Analgesic)

Methyl Salicylate (NSAID) - 15% (External Analgesic)

External Analgesic

Uses:

For temporary relief of the 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 immediately.

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

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

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

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:

Acrylates/C10-30 Alkyl Acrylate Crosspolymer, Aminomethylpropanol, Arnica Montana Oil, Dimethyl Sulfoxide, Ethylhexylglycerin, Eucalyptus Oil, Glyceryl Monostearate, Glyceryl Stearate/PEG-100 Stearate, Isopropyl Myristate, Magnesium Hydroxide, Maritime Pine, Phenoxyethanol, Polysorbate 80, Tocopherol Acetate, Water

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

Questions?

info@asystem.com

Made in the USA ASYSTEM.com
Please Recycle #OwnTheSystem

**ASYSTEM
RADICAL RELIEF
GEL ROLL ON**

75ml (2.53 FL OZ)

Award-Winning
Clinical Strength Pain Relief

**Instant. Powerful.
Maximum Absorption.**

Roll cryosphere onto painful area until gel
is fully absorbed. Repeat as necessary.

ACTIVE INGREDIENTS:
MENTHOL - 10% (EXTERNAL ANALGESIC)
METHYL SALICYLATE - 15% (EXTERNAL ANALGESIC)

CAUTION: FOR EXTERNAL USE ONLY
IF GEL COMES IN CONTACT WITH HANDS,
WASH WITH SOAP AND WATER.

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Venice, CA USA 90291
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DRUG FACTS

Active Ingredients	Purpose
Menthol - 10.0%	(External Analgesic)
Methyl Salicylate (NSAID) - 15.0%	(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.

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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: Acrylates/C10-30 Alkyl Acrylate Copolymer, Aminomethylpropanol, Arnica Montana Oil, Dimethyl Sulfoxide, Ethylhexylglycerin, Eucalyptus Oil, Glycerol Monostearate, Glycerol Stearate/PEG-100 Stearate, Isopropyl Myristate, Magnesium Hydroxide, Maritime Pine, Phenoxethanol, Polysorbate 80, Tocopherol Acetate, Water

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

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

Distributed by ASYSTEM Inc.
819 Ocean Front Walk, Unit 4,
Venice, CA 90291

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Questions? info@asystem.com



HELPS WITH

-  PAIN
-  INFLAMMATION
-  JOINT MOBILITY
-  SPRAINS
-  ARTHRITIS
-  STIFFNESS

ASYSTEM

RADICAL RELIEF GEL ROLL-ON

Menthol, Methyl Salicylate, Arnica
Clinical Strength Pain Relief
for Muscles & Joints

75ml (2.53 FL OZ)
Developed and Made in USA

IT'S TIME TO GET RADICAL.

Sometimes, the only solution is to be radical.

Getting hurt is one of those times. And we're not just talking about the big hurts. We're talking about those times when you wake up and for no explicable reason you can't look over your shoulder.

So, we asked ourselves: "What's a truly radical solution to these painful situations?" And it turned out, it was actually the combination of a few radical moves.

First: Using 25% active ingredients (vs. the standard 5%). Second: Combining powerful actives with proven homeopathic ingredients. And finally: Engineering a zero-touch, stainless steel ball applicator called a 'Cryosphere'.

Yeah. That all sounded pretty radical to us. Say hello to the Radical Relief Gel Roll-On.

ASYSTEM.com



menthol, methyl salicylate gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:52261-4902
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	0.10 kg in 1 kg
METHYL SALICYLATE (UNII: LAV5U5022Y) (SALICYLIC ACID - UNII:O414PZ4LPZ)	METHYL SALICYLATE	0.15 kg in 1 kg

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
CARBOMER INTERPOLYMER TYPE A (ALLYL SUCROSE CROSSLINKED) (UNII: 59TL3WG5CO)	
MARITIME PINE (UNII: 50JZ5Z98QY)	
DIMETHYL SULFOXIDE (UNII: YOW8V9698H)	
ISOPROPYL MYRISTATE (UNII: 0RE8K4LNJS)	
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
ARNICA MONTANA FLOWER (UNII: OZ0E5Y15PZ)	
.ALPHA.-TOCOPHEROL ACETATE, DL- (UNII: WR1WPI7EW8)	
GLYCERYL STEARATE/PEG-100 STEARATE (UNII: RD25J5V947)	
EUCALYPTUS OIL (UNII: 2R04ONI662)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	
MAGNESIUM HYDROXIDE (UNII: NBZ3QY004S)	
AMINOMETHYLPROPANOL (UNII: LU49E6626Q)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:52261-4902-1	1 in 1 CARTON	07/03/2023	
1		0.075 kg in 1 BOTTLE, WTH APPLICATOR; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	07/03/2023	

Labeler - Cosco International, Inc. (016433141)

Registrant - Cosco International, Inc (016433141)

Establishment

Name	Address	ID/FEI	Business Operations
Cosco International, Inc		016433141	manufacture(52261-4902) , label(52261-4902) , pack(52261-4902)

Revised: 7/2023

Cosco International, Inc.