

RUGGED FIT PAIN RELIEF ROLL ON- menthol, methyl salicylate gel

SYSTEM4BOOK LLC

Menthol 3%, Methyl Salicylate 10%

Topical Analgesic

Temporarily relieves the minor aches and pain of muscles and joints associated with simple backache, arthritis, strains, sprains, and bruises.

For external use only.

Do not use on children under 12 years of age, with a heating pad (may blister skin), on wounds or damaged skin.

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

Stop use and ask a doctor if excessive irritation develops, symptoms last more than 7 days or clear up and occur again within a few days, condition worsens.

If swallowed, get medical help or contact a poison control center right away.

Adults and children 12 years of age or older: apply to affected area up to 3 to 4 times daily. Children under 12 years of age: consult a physician.

Water, alcohol, carbomer, DMDM Hydantoin, Iodopropynyl Butylcarbamate, PEG-40 Hydrogenated Caster Oil, Aesculus Hippocastanum Seed Extract, Centella Asiatica Leaf Extract, Arnica Montana Flowers Oil, Calendula Officinalis Flower Extract, Triethanolamine.

RUGGED FIT PAIN RELIEF ROLL-ON GEL

MENTHOL +
METHYL SALICYLATE
FORMULA

Muscles Joints Arthritis

100 ML / 3,38 FL OZ

DRUG FACTS

Active Ingredients

Menthol 2%	Topical analgesic
Methyl Salicylate 10%	Topical analgesic

Uses

Temporarily relieves minor aches and pains of muscles and joints associated with: •Simple backache •Arthritis •Strains •Sprains •Bruises

Warnings

For external use only

Do not use:

- On children under 12 years of age
- With a heating pad (may cause blistering)
- On wounds or damaged skin

When using this product:

- Do not bandage tightly
- Avoid contact with eyes or mucous membranes

Stop use and ask a doctor if:

- Excessive irritation develops
- Symptoms last more than 7 days or clear up and occur again within a few days
- Condition worsens

Directions

- Adults and children 12 years of age and older: Apply to affected area up to 3 to 4 times daily
- Children under 12 years of age: Consult a physician

Other Information

Store between 20°-30°C (50°-86°F)

Inactive Ingredients:

Water, alcohol, camphor, carbomer, DMDM Hydantoin, Iodopropynyl Butylcarbamate, PEG-40 Hydrogenated Castor Oil, Aesculus Hippocastanum Seed Extract, Centella Asiatica Leaf Extract, Arnica Montana Flowers Oil, Calendula Officinalis Flower Extract, Triethanolamine.

Distributed by:
BEAUTYVICE, A BRAND OF SYSTEM4BOOK LLC
2365 NW 70TH AVE, SUITE C10
MIAMI, FL 33122
info@beautyvice.com
MADE IN COLOMBIA



RUGGED FIT PAIN RELIEF ROLL ON

menthol, methyl salicylate gel

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:85826-040
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	Basis of Strength	Strength
MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	3 g in 100 mL
METHYL SALICYLATE (UNII: LAV5U5022Y) (SALICYLIC ACID - UNII:O414PZ4LPZ)	METHYL SALICYLATE	10 g in 100 mL

Inactive Ingredients	
Ingredient Name	Strength
ARNICA MONTANA FLOWER (UNII: OZ0E5Y15PZ)	
PEG-40 HYDROGENATED CASTOR OIL (UNII: 7YC686GQ8F)	
DMDM HYDANTOIN (UNII: BYR0546TOW)	
HORSE CHESTNUT (UNII: 3C18L6RJAZ)	
CALENDULA OFFICINALIS FLOWER (UNII: P0M7O4Y7YD)	
CAMPHOR (SYNTHETIC) (UNII: 5TJD82A1ET)	
IODOPROPYNYL BUTYLCARBAMATE (UNII: 603P14DHEB)	
TRIETHANOLAMINE (UNII: 9O3K93S3TK)	
WATER (UNII: 059QF0KO0R)	
ALCOHOL (UNII: 3K9958V90M)	
CENTELLA ASIATICA LEAF (UNII: 6810070TYD)	
CARBOMER 940 (UNII: 4Q93RCW27E)	

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:85826-040-10	300 mL in 1 BOTTLE; Type 0: Not a Combination Product	06/27/2025	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M017	06/27/2025	

Labeler - SYSTEM4BOOK LLC (096336844)

Registrant - Maximsuramerica SAS (886586033)

Establishment

Name	Address	ID/FEI	Business Operations
Maximsuramerica SAS		886586033	manufacture(85826-040)

Revised: 6/2025

SYSTEM4BOOK LLC