MYGRIN ROLL-ON- menthol gel
Sunascen Therapeutics 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.

MYGRIN ® Roll-On Gel (Menthol 3.5% USP)

ACTIVE INGREDIENTS

Menthol, USP 3.5%

PURPOSE

External Analgesic (Cooling Pain Relief)

INDICATIONS AND USAGE

For the temporary relief of minor aches and pains of muscles and joints associated with arthritis, backache, bruises, strains, and sprains.

WARNINGS

For external use only

Flammable

Keep away from excessive heat or open flame

When using this product,

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

Ask a doctor before use if you have,

- Sensitive skin

Stop use and ask a doctor if,

- Conditions worsens
- Symptoms persist for more than 7 days
- Condition clears up and reoccurs

If pregnant or breastfeeding,

ask a health professional before use.

Keep out of the reach of children

If ingested, seek medical attention or contact a Poison Control Center immediately at 1-800-222-1222.
Prompt medical attention is critical for adults as well as for children even if you do not notice any signs or symptoms.

DOSAGE AND ADMINISTRATION (Directions)

Adults and Children 2 years of age and older: Apply to the affected areas not more than four times daily.
Children under 2 years of age: Consult a Physician.
Shake well before each use.

KEEP OUT OF REACH OF CHILDREN

If ingested, seek medical help right away or contact a Poison Control Center immediately.
Call Poison Control at 1-800-222-1222.
Prompt medical attention is critical for adults as well as for children even if you do not notice any signs or symptoms.

OTHER INFORMATION

- Apply product directly onto sore areas
- Massage well for best results
- Wash hands well, before and after application using cool water
- Store at room temperature
- Use before the expiration date

INACTIVE INGREDIENTS

Aloe barbadensis leaf extract, angelica archangelica root extract, camphor, carbomer, DMDM hydantoin, isopropyl alcohol, methylparaben, panax ginseng root extract, purified water, triethanolamine.

QUESTIONS OR COMMENTS?

Sunascen Therapeutics LLC
Call us toll free at 1-833-SUNASCN (786-2726) Mon-Fri 9am-5pm EST.

Email us at ConsumerCare@Sunascen.com
More information is available on our website at www.sunascen.com

PRINCIPAL DISPLAY PANEL

Sunascen Therapeutics LLC

NDC 49467-210-03

MYGRIN ® Roll-On Gel
SOOTHING MENTHOL - COOLING PAIN RELIEF
Arthritis, Back Pain, Sore Muscles & Joints
Non-Greasy, Dye-Free, and Non-Staining
With Aloe
3 fl oz (90mL)

SHAKE WELL BEFORE EACH USE
FOR EXTERNAL USE ONLY

Does not contain NSAIDs, Ibuprofen, Aspirin, or Salicylate

"Helping you turn the face of pain into a grin" ™

TAMPER EVIDENT: DO NOT USE IF THE SAFETY SEAL ON THE CARTON IS BROKEN OR MISSING

RETAIN CARTON FOR COMPLETE PRODUCT INFORMATION

Distributed by: Sunascen Therapeutics LLC, Rockville MD 20850-6252

Sunascen Therapeutics LLC
Quality Guaranteed
Please Recycle

MYGRIN ROLL-ON

menthol gel

Product Information

Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:49467-210
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	35 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
ANGELICA ARCHANGELICA ROOT (UNII: DTN01M69SN)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
CAMPHOR (NATURAL) (UNII: N20HL7Q941)	
CARBOMER HOMOPOLYMER TYPE C (UNII: 4Q93RCW27E)	
DMDM HYDANTOIN (UNII: BYR0546TOW)	
ISOPROPYL ALCOHOL (UNII: ND2M416302)	

METHYLPARABEN (UNII: A2I8C7HI9T)	
ASIAN GINSENG (UNII: CUQ3A77YXI)	
WATER (UNII: 059QF0KO0R)	
TROLAMINE (UNII: 9O3K93S3TK)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:49467-210-03	1 in 1 CARTON	02/05/2018	
1		90 mL in 1 BOTTLE, WITH 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	02/05/2018	

Labeler - Sunascen Therapeutics LLC (078272834)

Registrant - Sunascen Therapeutics LLC (078272834)

Establishment

Name	Address	ID/FEI	Business Operations
Sunascen Therapeutics LLC		078272834	label(49467-210)

Revised: 1/2023 Sunascen Therapeutics LLC