

THERALAST MAXIMUM STRENGTH PAIN RELIEF GEL- menthol gel

SKIN SHERPA NORTH AMERICA 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.

Theralast Maximum Strength Pain Relief Gel

Drug Facts

Active ingredient

Menthol 4%

Purpose

Topical analgesic

Uses

For the temporary relief of minor aches and pains of muscles and joints associated with:

- simple backache
- strains
- sprains
- bruises
- arthritis

Warnings

For external use only.

Do not use

- on large areas of the body
- with other ointments, creams, sprays or liniments
- with heating pad

Ask a doctor before use if you have

sensitive skin or redness over the affected area

When using this product

- avoid contact with eyes or mucus membranes
- do not apply to wounds or damaged skin
- do not bandage
- wash hands after use

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

If pregnant or breast-feeding

ask a health professional before use.

Keep out of reach of children.

If accidentally ingested, get medical help or contact a Poison Control Center immediately.

Directions

- Use only as directed
- **Adults and children over 12 years:** apply to affected area not more than 4 times daily.
- **Children under 12 years of age:** Consult physician.

Other information

Store in cool dry place

Inactive ingredients

Alcohol Denat., Aloe Barbadensis Leaf Juice, Arnica Montana Flower Extract, Butylene Glycol, Diethyl Azelate, Hydroxyethyl Acrylate/Sodium Acryloyldimethyl Taurate Copolymer, Isopropyl Alcohol, Methyl Hydroxypropyl Cellulose, Polyacrylate Crosspolymer 6, Polysorbate 20, Water

Questions?

1-833-499-0932 or theralast.com

Company Information

Distributed by Skin Sherpa North America, LLC, 18756 Stone Oak Parkway, Ste. 200 San Antonio, TX 78258

www.theralast.com

Product Packaging

**LONG LASTING PAIN RELIEF
FOR MUSCLES, JOINTS AND
CHRONIC ACHES**

IMPROVES MOBILITY AND REDUCES RECOVERY TIME

NECK PAIN
SHOULDERS
BACKACHE
JOINT PAIN
SORE MUSCLES
KNEE PAIN

NDC 80967-003-01

FAST ACTING
DEEP PENETRATING
NON-GREASY

3.4 FL OZ (100 ml)

**UP TO 12
HOURS OF
PAIN RELIEF***

THERALASTTM
UP TO 12 HOURS OF PAIN RELIEF*
MAXIMUM STRENGTH PAIN RELIEF GEL

TheralastTM Molecular Technology Stops Pain At The Source
Our patent pending molecular technology helps the cells of the body reverse inflammatory issues and relieve chronic muscle and joint pain. TheralastTM is made from safe ingredients and specially formulated to penetrate deep into the tissue for long lasting relief.

RECOMMENDED BY PHYSICIANS, PHYSICAL THERAPISTS, & CHIROPRACTORS

Does not contain NSAIDs, Aspirin or Salicylate. Paraben-Free. GMO-Free.

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

When using this product ■ avoid contact with eyes or mucous membranes ■ do not apply to wounds or damaged skin ■ do not bandage ■ wash hands after use

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

If pregnant or breast-feeding, ask a health professional before use. Keep out of reach of children. If accidentally ingested, get medical help or contact a Poison Control Center immediately.

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Inactive Ingredients: Alcohol Denat., Aloe Barbadensis Leaf Juice, Arnica Montana Flower Extract, Butylene Glycol, Diethyl Nonanedioate, Hydroxyethyl Acrylate/Sodium Acryloyldimethyl Taurate Copolymer, Isopropyl Alcohol, Methyl Hydroxypropyl Cellulose, Polyacrylate Crosspolymer 6, Polysorbate 20, Water

Questions: 1-833-499-0932 or theralast.com

*Performance claims based on patient surveys

GMP | Quality manufactured in a GMP certified facility.

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THERALAST MAXIMUM STRENGTH PAIN RELIEF GEL

menthol gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:80967-003
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	40 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
AMMONIUM ACRYLOYLDIMETHYLTAURATE, DIMETHYLACRYLAMIDE, LAURYL METHACRYLATE AND LAURETH-4 METHACRYLATE COPOLYMER, TRIMETHYLOLPROPANE TRIACRYLATE CROSSLINKED (45000 MPA.S) (UNII: Q7UI015FF9)	
ALCOHOL (UNII: 3K9958V90M)	
POLYSORBATE 20 (UNII: 7T1F30V5YH)	
WATER (UNII: 059QF0K00R)	
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)	
DIETHYL AZELATE (UNII: 4E9QQ39A4X)	
ISOPROPYL ALCOHOL (UNII: ND2M416302)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
BUTYLENE GLYCOL (UNII: 3XUS85K0RA)	
ARNICA MONTANA FLOWER (UNII: OZ0E5Y15PZ)	
HYDROXYETHYL ACRYLATE/SODIUM ACRYLOYLDIMETHYL TAURATE COPOLYMER (100000 MPA.S AT 1.5%) (UNII: 86FQE96TZ4)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:80967-003-01	1 in 1 BOX	02/22/2022	
1		100 mL in 1 TUBE; Type 0: Not a Combination Product		
2	NDC:80967-003-03	3 in 1 BOX	02/22/2022	
2		3 mL in 1 PACKET; Type 0: Not a Combination Product		
3	NDC:80967-003-10	10 in 1 BOX	02/22/2022	
3		3 mL in 1 PACKET; Type 0: Not a Combination Product		
4	NDC:80967-003-20	20 in 1 BOX	02/22/2022	
4		3 mL in 1 PACKET; 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	02/22/2022	

Labeler - SKIN SHERPA NORTH AMERICA LLC (117719003)