

THERALAST CLINICAL STRENGTH MD3 TOPICAL ANALGESIC- 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 Clinical Strength MD3 Topical Analgesic 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 Nonanedioate, Hydroxyethyl Acrylate/Sodium Acryloyldimethyl Taurate Copolymer, Isopropyl Alcohol, Hypromellose, Polysorbate 20, Water

Questions?

Call (210) 281-1056 MON-FRI 9AM-5PM CST

Company Information

Distributed by Skin Sherpa North America, LLC, San Antonio, TX 78216

Product Packaging

THERALAST

CLINICAL STRENGTH

MD3

TOPICAL ANALGESIC GEL

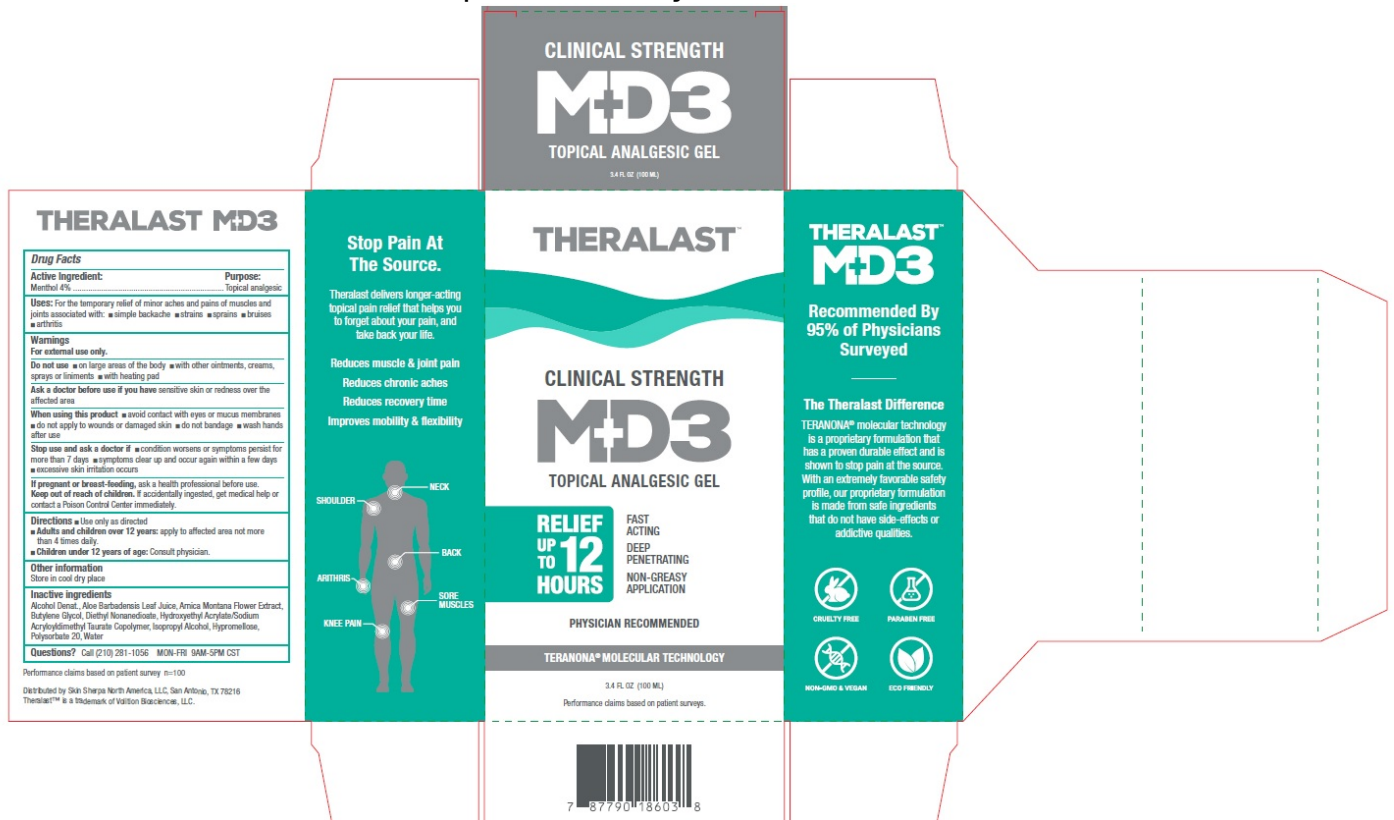
RELIEF UP TO 12 HOURS

FAST ACTING

DEEP PENETRATING
 NON-GREASY APPLICATION
 PHYSICIAN RECOMMENDED
 TERANONA® MOLECULAR TECHNOLOGY

3.4 FL OZ (100 ML)

Performance claims based on patient surveys.



THERALAST CLINICAL STRENGTH MD3 TOPICAL ANALGESIC

menthol gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:80967-002
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
ALCOHOL (UNII: 3K9958V90M)	
POLYSORBATE 20 (UNII: 7T1F30V5YH)	

WATER (UNII: 059QF0KO0R)
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:80967-002-01	1 in 1 BOX	11/15/2020	
1		100 mL in 1 BOTTLE, PUMP; 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	11/15/2020	

Labeler - SKIN SHERPA NORTH AMERICA LLC (117719003)

Revised: 8/2021

SKIN SHERPA NORTH AMERICA LLC