MD80 CLINICAL STRENGTH 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.

MD80 CLINICAL STRENGTH 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 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.

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, Methyl Hydroxypropyl Cellulose, Polyacrylate Crosspolymer 6, Polysorbate 20, Water

Questions?

1-806-319-8845 or md80relief.com

Company Information

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

www.md80relief.com

Product Packaging

MD80 CLINICAL STRENGTH TOPICAL ANALGESIC

menthol gel

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:80967-004
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: 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:80967-004-01	1 in 1 BOX	05/02/2022	
1		100 mL in 1 TUBE; Type 0: Not a Combination Product		
2	NDC:80967-004-03	3 in 1 BOX	05/02/2022	
2		3 mL in 1 PACKET; Type 0: Not a Combination Product		
3	NDC:80967-004-10	10 in 1 BOX	05/02/2022	
3		3 mL in 1 PACKET; Type 0: Not a Combination Product		
4	NDC:80967-004-20	20 in 1 BOX	05/02/2022	
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	05/02/2022	

Labeler - SKIN SHERPA NORTH AMERICA LLC (117719003)

Revised: 5/2022 SKIN SHERPA NORTH AMERICA LLC