

COOLING- menthol gel
FULL EIGHT LLC

FULL EIGHT - COOLING GEL (82551-119)

ACTIVE INGREDIENT

MENTHOL 1.2%

PURPOSE

TOPICAL ANALGESIC

USE

Temporary relief from minor aches and pain such as cramps, sore muscles, arthritis, muscle strains, and bruises

WARNINGS

For external use only

Flammable: Keep away from excessive heat and open flame

Ask a doctor before use if you have: Sensitive skin

When using this product: Avoid contact with eyes or mucous membranes

- Do not apply to wounds or damaged skin
- Do not use with other ointments, creams, sprays, or liniments
- Do not apply to irritated skin or if excessive irritation develops
- Do not bandage
- Wash hands after use with cool water
- Do not use with heating pad or device

Stop use and ask a doctor if: Condition worsens, or if symptoms persist for more than 7 days, or clear up and recur

If pregnant or breast-feeding: Ask a doctor before use

KEEP OUT OF REACH OF CHILDREN.

DIRECTIONS

Adults 18 years of age and older: Massage into skin at affected areas before bed & when symptoms arise

INACTIVE INGREDIENTS

Purified water, Glycerin, SD Alcohol, Carbomer, Olive Oil, Tetrasodium EDTA, Spearmint Oil, Lemongrass oil, Eucalyptus Oil, Peppermint Oil, Camphor, Triethanolamine, F D & C Blue #1, DMDM Hydantoin

QUESTIONS OR COMMENTS?

704-461-3009 • help@fulleight.com

fulleight[®]
the sleep company

**cooling
gel**

FAST ACTING PAIN RELIEF
with TURMERIC, MENTHOL & ALOE

REST BETTER



118 ML (4 OZ)

DRUG FACTS

ACTIVE INGREDIENTS	PURPOSE
Menthol 1.2%	Topical Analgesic

USES: Temporary relief from minor aches and pain such as cramps, sore muscles, arthritis, muscle strains, and bruises

WARNINGS

For external use only

FLAMMABLE: Keep away from excessive heat and open flame

ASK A DOCTOR BEFORE USE IF YOU HAVE: Sensitive skin

WHEN USING THIS PRODUCT: Avoid contact with eyes or mucous membranes • Do not apply to wounds or damaged skin • Do not use with other ointments, creams, sprays, or liniments • Do not apply to irritated skin or if excessive irritation develops • Do not bandage • Wash hands after use with cool water • Do not use with heating pad or device

STOP USE AND ASK A DOCTOR IF: Condition worsens, or if symptoms persist for more than 7 days, or clear up and recur

IF PREGNANT OR BREAST-FEEDING: Ask a doctor before use

KEEP OUT OF REACH OF CHILDREN

DIRECTIONS: Adults 18 years of age and older:
Massage into skin at affected areas before bed & when symptoms arise

INACTIVE INGREDIENTS: Aqua, Ethanol, Glycerin, Menthol, Cymbopogon Citratus (Lemongrass) Leaf Oil, Olea Europaea (Olive) Fruit Oil, Glyceryl Caprylate, Glyceryl Undecylenate, Carbomer, Eucalyptus Globulus Leaf Oil, Aminomethyl Propanol, Tetrasodium EDTA, Mentha Spicata (Spearmint) Oil, Blue #1 (CI 42090)

QUESTIONS OR COMMENTS: 704-461-3009 • help@fulleight.com

NDC 82551-119-14

Does not contain NSAIDs,
Ibuprofen, Aspirin,
or Salicylate.

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Questions?
info@fulleight.com

fulleight.com
Made in the USA



COOLING

menthol gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:82551-119
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	1.2 g in 100 mL

Inactive Ingredients

Ingredient Name	Strength
CAMPHOR OIL (UNII: 75IZZ8Y727)	
TROLAMINE (UNII: 9O3K93S3TK)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
DMDM HYDANTOIN (UNII: BYR0546TOW)	
WATER (UNII: 059QF0KO0R)	
ALCOHOL (UNII: 3K9958V90M)	
CARBOMER HOMOPOLYMER, UNSPECIFIED TYPE (UNII: 0A5MM307FC)	
OLIVE OIL (UNII: 6UYK2W1W1E)	
EDETATE SODIUM TETRAHYDRATE (UNII: L13NHD21X6)	
GLYCERIN (UNII: PDC6A3C0OX)	
SPEARMINT OIL (UNII: C3M81465G5)	
EAST INDIAN LEMONGRASS OIL (UNII: UP0M8M3VZW)	
EUCALYPTUS OIL (UNII: 2R04ONI662)	
PEPPERMINT OIL (UNII: AV092KU4JH)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:82551-119-14	118 mL in 1 BOTTLE; Type 0: Not a Combination Product	01/26/2022	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M017	01/26/2022	

Labeler - FULL EIGHT LLC (096786623)