

**COOLING- menthol gel**  
**FULL EIGHT Inc**

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**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**<sup>®</sup>  
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

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

**Active Ingredient/Active Moiety**

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

**Inactive Ingredients**

Ingredient Name	Strength
<b>CAMPHOR OIL</b> (UNII: 75IZZ8Y727)	
<b>TROLAMINE</b> (UNII: 9O3K93S3TK)	
<b>FD&amp;C BLUE NO. 1</b> (UNII: H3R47K3TBD)	
<b>DMDM HYDANTOIN</b> (UNII: BYR0546TOW)	
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>ALCOHOL</b> (UNII: 3K9958V90M)	
<b>CARBOMER HOMOPOLYMER, UNSPECIFIED TYPE</b> (UNII: 0A5MM307FC)	
<b>OLIVE OIL</b> (UNII: 6UYK2W1W1E)	
<b>EDETATE SODIUM TETRAHYDRATE</b> (UNII: L13NHD21X6)	
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	
<b>SPEARMINT OIL</b> (UNII: C3M81465G5)	
<b>EAST INDIAN LEMONGRASS OIL</b> (UNII: UP0M8M3VZW)	
<b>EUCALYPTUS OIL</b> (UNII: 2R04ONI662)	
<b>PEPPERMINT OIL</b> (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 Inc (096786623)**