

MENTHOLATUM CHILDRENS NIGHTTIME VAPORIZING RUB- camphor, eucalyptus oil, menthol ointment

The Mentholatum Company

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.

Drug Facts

Active ingredients

Camphor 5.3%

Eucalyptus oil 1.3%

Menthol 2.8%

Purpose

Camphor - Cough suppressant / topical analgesic

Eucalyptus oil - Cough suppressant

Menthol - Cough suppressant / topical analgesic

Uses

- temporarily relieves cough due to minor throat and bronchial irritation associated with a cold
- temporarily relieves cough to help you sleep
- temporarily relieves minor aches and pains of muscles and joints

Warnings

For external use only

Ask a doctor before use if you have

- cough that occurs with too much phlegm (mucus)
- chronic cough that lasts or as occurs with smoking, asthma, or emphysema

When using this product

- **do not heat, microwave, or add to hot water or any container where heating water. May cause splattering and result in burns.**
- do not take by mouth or place in nostrils
- do not bandage tightly
- do not get into eyes
- do not apply to wounds or damaged skin

Stop use and ask a doctor if

- cough lasts more than 7 days, comes back, or occurs with fever, rash, or headache that lasts. These could be signs of a serious condition.
- muscle aches and pains persist for more than 7 days or clear up and occur again within a few days

Keep out of reach of children.

If swallowed, get medical help or contact a Poison Control Center right away.

Directions

- **see important warning under "When using this product"**
- adults and children 2 years and over:
- rub a thick layer on the throat and chest for cough, or rub on sore, aching muscles or joints
- cover with a warm, dry cloth if desired
- clothing should be left loose about the throat and chest to help vapors reach the nose and mouth
- use up to 3 times daily, or as directed by a doctor
- children under 2 years: ask a doctor

Inactive ingredients

carthamus tinctorius (safflower) seed oil, chamomilla recutita (matricaria) flower, fragrance, lavandula angustifolia (lavender) flower, rosmarinus officinalis (rosemary) leaf oil, white petrolatum

Questions?

1-877-636-2677 MON-FRI 9 AM to 5 PM (EST)

Package/Label Principal Display Panel



MENTHOLATUM CHILDRENS NIGHTTIME VAPORIZING RUB

camphor, eucalyptus oil, menthol ointment

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:10742-1112
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
CAMPHOR (NATURAL) (UNII: N20HL7Q941) (CAMPHOR (NATURAL) - UNII:N20HL7Q941)	CAMPHOR (NATURAL)	53 mg in 1 g
EUCALYPTUS OIL (UNII: 2R04ONI662) (EUCALYPTUS OIL - UNII:2R04ONI662)	EUCALYPTUS OIL	13 mg in 1 g
MENTHOL, UNSPECIFIED FORM (UNII: L7T10EIP3A) (MENTHOL, UNSPECIFIED FORM - UNII:L7T10EIP3A)	MENTHOL, UNSPECIFIED FORM	28 mg in 1 g

Inactive Ingredients

Ingredient Name	Strength
SAFFLOWER OIL (UNII: 65UEH262IS)	
CHAMOMILE (UNII: FGL3685T2X)	
LAVANDULA ANGUSTIFOLIA SUBSP. ANGUSTIFOLIA FLOWER (UNII: 19AH1RAF4M)	
ROSEMARY OIL (UNII: 8LGU7VM393)	
PETROLATUM (UNII: 4T6H12BN9U)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:10742-1112-1	1 in 1 CARTON	08/01/2018	
1		50 g in 1 JAR; Type 0: Not a Combination Product		
2	NDC:10742-1112-2	1 in 1 CARTON	11/18/2019	
2		85 g in 1 JAR; Type 0: Not a Combination Product		
3	NDC:10742-1112-3	1 in 1 CARTON	10/19/2020	
3		57.5 g in 1 JAR; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	08/01/2018	

Labeler - The Mentholatum Company (002105757)

Registrant - The Mentholatum Company (002105757)

Establishment

Name	Address	ID/FEI	Business Operations
The Mentholatum Company		002105757	manufacture(10742-1112)

Revised: 2/2023

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