

ASTONEA CHEST RUB- camphor (synthetic), eucalyptus oil, and menthol ointment

ASTONEA LABS PRIVATE LIMITED

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.

ASTONEA ChestRub

Drug Facts

Active ingredients

Camphor 4.7%

Menthol 1.25%

Eucalyptus oil 1.2%

Purpose

Cough suppressant & Topical Analgesic

Cough suppressant

Cough suppressant & Topical Analgesic

Uses

- when applied to chest and throat, temporarily relieves cough due to minor throat and bronchial irritation associated with the common cold
- when applied to muscles and joints, temporarily relieves minor aches and pains of muscles and joints

Warnings

For external use only; avoid contact with eyes.

Do not use

- by mouth
- with tight bandages
- in nostrils
- on wounds or damaged skin

Ask a doctor before use if you have

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

When using this product, do not

- heat
- microwave
- add to hot water or any container where heating water.
May cause splattering and result in burns.

Stop use and ask a doctor if

- muscle aches and pains persist more than 7 days or come back
- cough lasts for more than 7 days, comes back, or occurs with fever, rash, or persistent headache. A persistent cough may be a sign of a serious condition.

If pregnant or breast-feeding, ask a health professional before use.

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

Directions

see important warnings under " When using this product"

- adults and children 2 years and over
- rub a thick layer on throat & chest &
- cover with a warm, dry cloth if desired
- keep clothing loose about throat and chest to help vapors reach the nose and mouth
- use up to three times daily or as directed by doctor
- for muscle/joint minor aches and pains apply to affected area not more than 3 to 4 times daily
- children under 2 years: do not use

Other information

- store at room temperature

Inactive ingredients

cedar leaf oil, methylparaben, nutmeg oil, petrolatum, propylparaben, thymol, turpentine oil

PRINCIPAL DISPLAY PANEL

ASTONEA

ChestRub

COUGH SUPPRESSANT TOPICAL ANALGESIC

Net Wt.: 4 oz. (113g)

Drug Facts

Active ingredients
 Camphor 4.7% w/w Cough suppressant & topical analgesic
 Menthol 1.25% w/w Cough suppressant
 Eucalyptus Oil 1.2% w/w Cough suppressant & topical analgesic

Purpose
 ■ when applied to chest or throat, temporarily relieves cough due to minor throat and bronchial irritation associated with the common cold
 ■ when applied to muscles and joints, temporarily relieves minor aches and pains of muscles and joints

Uses
 ■ when applied to chest or throat, temporarily relieves cough due to minor throat and bronchial irritation associated with the common cold
 ■ when applied to muscles and joints, temporarily relieves minor aches and pains of muscles and joints

Warnings
For external use only; avoid contact with eyes.
 ■ do not use ■ by mouth ■ with tight bandages
 ■ in nostrils ■ on wounds or damaged skin
Ask a doctor before use if you have
 ■ cough that occurs with too much phlegm (mucus) ■ persistent or chronic cough such as occurs with smoking, asthma or emphysema

When using this product
 do not ■ heat ■ microwave ■ add to hot water or any container where heating water.
 May cause splattering and result in burns.

Stop use and ask a doctor if ■ muscle aches and pains persist more than 7 days or come back
 ■ cough lasts more than 7 days, comes back, or occurs with fever, rash, or persistent headache.
 These could be signs of a serious condition

If pregnant or breast-feeding, ask a health professional before use.
KEEP OUT OF REACH OF CHILDREN
 If swallowed get medical help or contact a Poison Control Center right away.

Directions
See important warnings under "When using this product"
 ■ adults and children 2 years and over ■ rub a thick layer on throat & chest ■ cover with a warm, dry cloth if desired ■ keep clothing loose around throat and chest to help vapors reach the nose and mouth
 ■ use up to three times daily or as directed by a doctor ■ for muscle / joint minor aches and pains apply to affected area not more than 3 to 4 times daily ■ children under 2 years do not use

Other information ■ store at room temperature

Inactive ingredients cedar leaf oil, methylparaben, nutmeg oil, petrolatum, propylparaben, thymol, turpentine oil.

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LOT NO.:
 MFG. DT.:
 EXP. DT.:

ASTONEA CHEST RUB

camphor (synthetic), eucalyptus oil, and menthol ointment

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:77338-321
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
CAMPHOR (SYNTHETIC) (UNII: 5TJD82A1ET) (CAMPHOR (SYNTHETIC) - UNII:5TJD82A1ET)	CAMPHOR (SYNTHETIC)	0.047 g in 1 g
EUCALYPTUS OIL (UNII: 2R04ONI662) (EUCALYPTUS OIL - UNII:2R04ONI662)	EUCALYPTUS OIL	0.012 g in 1 g
MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	0.0125 g in 1 g

Inactive Ingredients

Ingredient Name	Strength
CEDAR LEAF OIL (UNII: BJ169U4NLG)	
NUTMEG OIL (UNII: Z1CLM48948)	
THYMOL (UNII: 3J50XA376E)	
TURPENTINE OIL (UNII: C5H0QJ6V7F)	
PETROLATUM (UNII: 4T6H12BN9U)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:77338-321-21	113 g in 1 JAR; Type 0: Not a Combination Product	04/08/2019	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	04/05/2019	

Labeler - ASTONEA LABS PRIVATE LIMITED (878533295)