

HEALTH SMART VAPORIZING CHEST RUB- menthol and camphor and eucalyptus oil gel **Home Smart Products**

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.

Active Ingredients

Camphor	4.7%
Menthol	1.0%
Eucalyptus Oil	1.0%

Purpose

Cough Suppressant
Topical Analgesic
Nasal Decongestant

Uses

- On chest and throat, helps temporarily relieve cough as may occur with common cold and minor bronchial irritation.
- For the temporary relief of pain associated with minor skin irritation.

Warnings

For external use only. Avoid contact with eyes.

Do not take by mouth or place in nostrils.

Do not use

- by mouth
- in nostrils
- with tight bandages
- on wounds or damaged skin
- with persistent or chronic cough such as occurs with asthma, emphysema or smoking

Ask doctor if you have,

- cough that occurs with too much phlegm (mucus)

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:

- cough that lasts more than 7 days, comes back, or occurs with fever, rash or persistent headache.
These could be signs of a serious conditions

Keep out of the reach of children

If ingested get medical help or contact a Poison control center immediately

Directions: see important warnings under “When using this product”

adults and children 2 years and over:

- rub a thick layer on chest and throat

- keep clothing loose around chest/throat to help vapors reach the nose/mouth
- use up to 3 times daily as directed by doctor

children under 2 years of age: ask a doctor

Inactive Ingredients

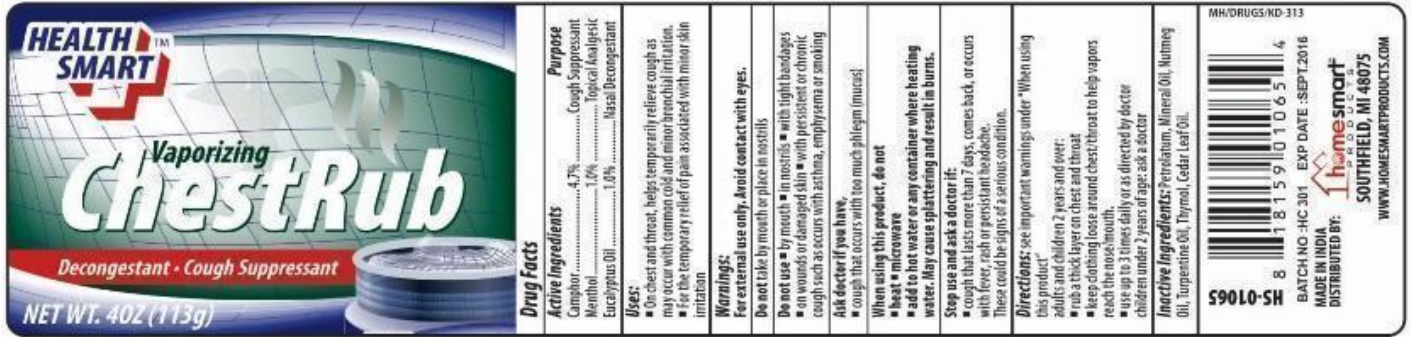
Petrolatum, Mineral Oil, Nutmeg Oil, Turpentine Oil, Thymol, Cedar Leaf Oil

PRINCIPAL DISPLAY PANEL

HEALTH SMART VAPORISING CHEST RUB GEL

DECONGESTANT AND COUGH SUPPRESSANT

NET WT. 4 OZ (113g)



HEALTH SMART VAPORIZING CHEST RUB

menthol and camphor and eucalyptus oil gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:52862-040
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
CAMPHOR (SYNTHETIC) (UNII: 5TJD82A1ET) (CAMPHOR (SYNTHETIC) - UNII:5TJD82A1ET)	CAMPHOR (SYNTHETIC)	4.7 g in 100 g
MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	1.25 g in 100 g
EUCALYPTUS OIL (UNII: 2R04ONI662) (EUCALYPTUS OIL - UNII:2R04ONI662)	EUCALYPTUS OIL	1.2 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
CEDAR LEAF OIL (UNII: BJ169U4NLG)	
NUTMEG OIL (UNII: Z1CLM48948)	
MINERAL OIL (UNII: T5L8T28FGP)	
PETROLATUM (UNII: 4T6H12BN9U)	
THYMOL (UNII: 3J50XA376E)	
TURPENTINE OIL (UNII: C5H0QJ6V7F)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:52862-040-19	50 g in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	08/01/2020	
2	NDC:52862-040-31	56.6 g in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	08/01/2020	
3	NDC:52862-040-20	100 g in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	08/01/2020	
4	NDC:52862-040-14	113 g in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	08/01/2020	
5	NDC:52862-040-32	150 g in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	08/01/2020	
6	NDC:52862-040-21	170 g in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	08/01/2020	
7	NDC:52862-040-01	226 g in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	08/01/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	10/01/2013	

Labeler - Home Smart Products (161872676)

Registrant - Anicare Pharmaceuticals Pvt. Ltd (916837425)

Establishment

Name	Address	ID/FEI	Business Operations
Jell Pharmaceuticals Pvt. Ltd.		726025211	manufacture(52862-040)

Establishment

Name	Address	ID/FEI	Business Operations
Anicare Pharmaceuticals Pvt. Ltd		916837425	manufacture(52862-040)

Revised: 8/2020

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