DR WALTONS VAPOR RUB - vapor rub gel DR. WALTONS, INCORPORATED

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.

DR. WALTONS VAPOR RUB

ACTIVE INGREDIENTS

Active Ingredient: Purpose:

Menthol: 2.0% Cough suppressant and topical analgesic

Camphor: 4.7% Cough suppressant

Eucalyptus Oil: 1.0% Cough suppressant and topical analgesic

ASK DOCTOR

Consult a physician before use: If you have asthma, emphysema, persistent or chronic cough, cough associated with smoking or excessive mucus. If muscle aches persist for more than 7 days or come back or if cough lasts more than 7 days, comes back or occurs with fever, rash or a persistent headache.

DO NOT USE

WARNING: For external use only. Not for internal use. Avoid contact with eyes. Do not put in mouth, nostrils or on wounds or damaged skin.

KEEP OUT OF REACH OF CHILDREN

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

PREGNANCY OR BREAST FEEDING

If pregnant or breast feeding: Consult a physician before use. Do not use near open flame, in a microwave oven or in a container in which water is being heated except when adding to cold water in a hot steam vaporizer.

PURPOSE

Uses: On chest and throat, temporarily relieves cough and nasal congestion due to common cold. On muscles and joints, temporarily relieves minor aches and pains.

WHEN USING

Directions: Adults and children 2 years of age and older rub thick layer on chest and throat for temporary relief from nasal congestion and coughing due to colds or rub on sore, aching muscles. If desired, loosely cover with a soft dry cloth but keep clothing loose. Repeat up to three times daily, especially at bedtime. For children under 2 years of age, consult a physician.

DR. WALTON'S VAPOR RUB



PETROLATUM, MINERAL OIL, NUTMEG OIL, TURPENTINE OIL, THYMOL, CEDAR LEAF OIL

ON CHEST AND THROAT, TEMPORARILY RELIEVES COUGH AND NASAL CONGESTION DUE TO COMMON COLD. ON MUSCLES AND JOINTS, TEMPORARILY RELIEVES MINOR ACHES AND PAINS.

DR WALTONS VAPOR RUB

vapor rub gel

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:76271-004
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety				
Ingredient Name	Basis of Strength	Strength		
CAMPHOR (SYNTHETIC) (UNII: 5TJD82A1ET) (CAMPHOR (SYNTHETIC) - UNII:5TJD82A1ET)	CAMPHOR (SYNTHETIC)	5.3 g in 113 g		
MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	2.26 g in 113 g		
EUCALYPTUS OIL (UNII: 2R04ONI662) (EUCALYPTUS OIL - UNII:2R04ONI662)	EUCALYPTUS OIL	1.13 g in 113 g		

Inactive Ingredients		
Ingredient Name	Strength	
PETRO LATUM (UNII: 4T6 H12BN9 U)		
MINERAL OIL (UNII: T5L8T28FGP)		
NUTMEG OIL (UNII: Z1CLM48948)		
TURPENTINE OIL (UNII: C5H0QJ6V7F)		
THYMOL (UNII: 3J50XA376E)		
CEDAR LEAF OIL (UNII: BJ169U4NLG)		

Packaging			
# Item Code	Package Description	Marketing Start Date	Marketing End Date
1 NDC:76271-004-04	113 g in 1 JAR		

Marketing Information					
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date		
OTC monograph final	part346	07/14/2011			

Labeler - DR. WALTONS, INCORPORATED (041377104)

Revised: 6/2011 DR. WALTONS, INCORPORATED