

ARHTRI PLUS - menthol,eucalyptus oil, clove oil spray

Distributions Ar?mes d`Espagne Enr

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

Menthol 2.5%

Eucalyptus oil (Eucalyptus globulus) (leaf) 0.72%

Clove Oil (Eugenia caryophyllatus) (leaf) 0.25%

Purpose

Topical Analgesic

Uses

For the temporary relief of aches and pains of muscles and joints associated with backache, lumbago, strains, bruises, sprains and arthritic or rheumatic pain, pain of tendons and ligaments.

Warnings

For external use only. Do not apply to wounds or damaged skin. Do not inhale. Avoid contact with eyes and mucous membranes. Discontinue use if rash or irritation occurs. The application of external heat, such as an electric heating pad, may result in excessive skin irritation or skin burn. Do not bandage. Keep away from heat, sparks and open flames.

Keep out of reach of children.

Directions

For adults and children 2 years of age and older: Shake well before use. Apply to the affected area not more than 3-4 times daily. Allow absorption to occur naturally for maximum penetration. If condition worsens, or if symptoms persist for more than 7 days or clear up and occur again within a few days, discontinue use of this product and consult a health care practitioner.

Inactive Ingredients

Camphor, Isopropyl Alcohol, Peppermint Oil, Purified Water

Other Information

Do not use if seal is broken.

Questions or comments?

1-888-331-3911 or www.fastactingpainrelief.com

Principal Display Panel

Made in Canada

+Arthri-Plus

Vaporisateur / Spray

NPN 80009727

Net Wt. 150 ml.

Made in Canada

+Arthri-Plus

Vaporisateur / Spray



NPN 80009727

Net Wt. 150 ml.

Drug Facts

Active Ingredients

Menthol 2.5%.....	Topical Analgesic
Eucalyptus oil (Eucalyptus globulus) (leaf) 0.72%.....	Topical Analgesic
Clove oil (Eugenia caryophyllatus) (leaf) 0.25%.....	Topical Analgesic

Purpose

Uses:

For the temporary relief of aches and pains of muscles and joints associated with backache, lumbago, strains, bruises, sprains and arthritic or rheumatic pain, pain of tendons and ligaments.

Warnings:

For external use only. Do not apply to wounds or damaged skin. Do not inhale. Avoid contact with eyes and mucous membranes. Discontinue use if rash or irritation occurs. The application of external heat, such as an electric heating pad, may result in excessive skin irritation or skin burn. Do not bandage. Keep away from heat, sparks and open flames. Keep out of reach of children.

Directions:

For adults and children over 2 years old. Shake well before use. Apply to the affected area not more than 3 to 4 times daily. Allow absorption to occur naturally for maximum penetration. If condition worsens, or if symptoms persist for more than 7 days or clear up and occur again within a few days discontinue use of this product and consult a health care practitioner.

Inactive Ingredients: Camphor, Isopropyl alcohol, peppermint oil, purified water.

Other Information: Do not use if seal is broken.

Questions or Comments?

1-888-331-3911 or www.fastactingpainrelief.com

Distributed by:

Distributions Arômes d'Espagne Enrg
9440 Route Transcanadienne,
St-Laurent, Qc Canada H4S 1R7

NDC 69320-100-01

ARHTRI PLUS

menthol, eucalyptus oil, clove oil spray

Product Information

Product Type

HUMAN OTC DRUG

Item Code (Source)

NDC:69320-100

Route of Administration TOPICAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	2.5 g in 100 g
EUCALYPTUS OIL (UNII: 2R04ONI662) (EUCALYPTUS OIL - UNII:2R04ONI662)	EUCALYPTUS OIL	0.72 g in 100 g
CLOVE OIL (UNII: 578389D6D0) (CLOVE OIL - UNII:578389D6D0)	CLOVE OIL	0.25 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
CAMPHOR (SYNTHETIC) (UNII: 5TJD82A1ET)	
ISOPROPYL ALCOHOL (UNII: ND2M416302)	
PEPPERMINT OIL (UNII: AV092KU4JH)	
WATER (UNII: 059QF0K00R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69320-100-01	150 g in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product	10/30/2014	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	10/30/2014	

Labeler - Distributions Ar?mes d`Espagne Enr (241070528)

Establishment

Name	Address	ID/FEI	Business Operations
Distributions Ar?mes d`Espagne Enr		241070528	manufacture(69320-100)

Revised: 9/2016

Distributions Ar?mes d`Espagne Enr