MAXXIMA- camphor and menthol lotion Dr. Knoll Products, Inc.

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.

Maxxima

Active Ingredients

Camphor 3.01%

Menthol 1.25%

Purpose

Topical analgesic

Topical analgesic

Uses for temporary relief of minor aches and pains of muscles and joints associated with

- simple backache
- arthritis
- strains
- sprains
- bruises

Warnings

For external use only

Do not use

- on children under 10 years of age
- on wounds or damaged skin

When using this product

- use only as directed
- do not bandage tightly
- avoid contact with eyes and open sores

Stop use and ask doctor if

- excessive redness or skin irritation is present
- condition worsens, or if symptoms persist for more than 7 days or clear up and occur again within a few days

If pregnant or breastfeeding, 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.

Other Information

store between 15 degrees and 30 degrees C (59 degrees to 86 degrees F)

Directions

- Shake well before use
- Adults and children 10 years of age and older:
- o apply to affected area not more than 3-4 times daily

- massage lightly into painful areas until thoroughly absorbed into the skin
- Children under 10 years of age consult a physician

Inactive ingredients

glycerin, water, hydroxypropylmethylcellulose, propylene glycol, aloe vera extract, lavender oil, tea tree oil, spruce oil, rosemary oil, sage oil, juniper berry oil, cajeput oil, peppermint oil, horse chestnut extract, methyl paraben, sodium copper chlorophyllin, propyl paraben

Manufactured for: Dr. Knoll Products, Inc.

374 Newton Street, P.O. Box 116, Canfield, OH 44406

TO REORDER: 1-800-2434

Maxxima

The Pain Relieving Cream

External Analgesic

with Camphor and Menthol

With Moisturizing Aloe

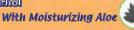
floz(ml)

For your protection, this bottle has an imprinted seal around the neck.



PAIN RELIEVING CREAM

EXTERNAL ANALGESIC with Camphor and Menthol



Net contents 4.0 fl oz (120 ml) For your protection, this bottle has an imprinted seal around the neck.

Drug Facts

Active ingredients Purpose Camphor 3.01%......Topical analgesic Menthol 1.25%.....Topical analgesic

Uses for temporary relief of minor aches and pains of muscles and joints associated with

- · simple backache · arthritis · strains
- · sprains · bruises

Warnings For external use only

Do not use

- · on children under 10 years of age
- · on wounds or damaged skin

When using this product

- · use only as directed
- do not bandage tightly
- avoid contact with eyes and open sores

Drug Facts (continued)

Stop use and ask a doctor if excessive redness or skin irritation

- condition worsens, or if symptoms
- persist for more than 7 days or clear up and occur again within a few days

If pregnant or breastfeeding, 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

- Shake Well Before Use
- Adults and children 10 years of age
- · apply to affected area not more than 3 to 4 times daily
- massage lightly into painful areas until thoroughly absorbed into the skin
- Children under 10 years of age consult a physician

Drug Facts (continued) Other information

store between 15°-30°C (59°-86°F)

Inactive ingredients glycerin, water, hydroxypropylmethylcellulose, propylene glycol, aloe vera extract, lavender oil, tea tree oil, spruce oil, rosemary oil, sage oil, juniper berry oil, cajeput oil, peppermint oil, horse chestnut extract, methyl paraben, sodium copper chlorophyllin, propyl paraben. paraben

Manufactured for:

Dr. Knoll Products, Inc.

374 Newton Street P.O. Box 116 Canfield, OH 44406

TO REORDER 1-800-877-2434



MAXXIMA

camphor and menthol lotion

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:50638-100
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
CAMPHOR (SYNTHETIC) (UNII: 5TJD82A1ET) (CAMPHOR (SYNTHETIC) - UNII:5TJD82A1ET)	CAMPHOR (SYNTHETIC)	3.01 g in 100 mL	
MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	1.25 g in 100 mL	

Inactive Ingredients		
Ingredient Name	Strength	
GLYCERIN (UNII: PDC6A3C0OX)		
WATER (UNII: 059QF0KO0R)		

I	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
ALOE VERA LEAF (UNII: ZY8 1Z8 3H0 X)	
LAVENDER O IL (UNII: ZBP1YXW0H8)	
TEA TREE OIL (UNII: VIF565UC2G)	
PICEA MARIANA LEAF O IL (UNII: Q1J49L1A5O)	
ROSEMARY OIL (UNII: 8LGU7VM393)	
SAGE OIL (UNII: U27K0H1H2O)	
JUNIPER BERRY O IL (UNII: SZH16H44UY)	
CAJUPUT OIL (UNII: J3TO6BUQ37)	
PEPPERMINT OIL (UNII: AV092KU4JH)	
HORSE CHESTNUT (UNII: 3C18L6RJAZ)	
METHYLPARABEN (UNII: A2I8 C7HI9 T)	
SODIUM COPPER CHLOROPHYLLIN (UNII: 1D276TYV9O)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	

Packaging				
	# Item Code	Package Description	Marketing Start Date	Marketing End Date
l	1 NDC:50638-100-02	60 mL in 1 BOTTLE; Type 0: Not a Combination Product	06/11/2012	
	2 NDC:50638-100-04	120 mL in 1 BOTTLE; Type 0: Not a Combination Product	06/11/2012	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	06/11/2012	

Labeler - Dr. Knoll Products, Inc. (121880975)

Establishment					
Name	Address	ID/FEI	Business Operations		
Vita-Herb Nutriceuticals, Inc.		053760034	manufacture(50638-100)		

Revised: 6/2012 Dr. Knoll Products, Inc.