

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:
 - ◦ 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

fl oz (ml)

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

MAXXIMA™

THE PAIN RELIEVING CREAM
EXTERNAL ANALGESIC
with Camphor and Menthol



With Moisturizing Aloe



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

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

Directions

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Drug Facts (continued)

Other information

- store between 15°–30°C (59°–86°F)

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Manufactured for:

Dr. Knoll Products, Inc.

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

**TO REORDER
1-800-877-2434**

MAXXIMA
THE PAIN RELIEVING CREAM
2.0 fl oz (60 mL)
3.2274243, 3.2274243, 3.2274243
With Menthol and Aloe
For pain relief, this cream has an ingredients list on the back.

Drug Facts
Active Ingredients Purpose
Camphor 3.01% Topical anesthetic
Menthol 1.25% Topical anesthetic

Uses for temporary relief of minor aches and pains of muscles and joints associated with:
• sprain • 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 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°-30°C (59°-86°F)

Drug Facts (continued)
Directions
• Shake well before use
• Adults and children 10 years of age and older:
• 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, capsaicin oil, peppermint oil, horse chestnut extract, methyl paraben, sodium copper chlorophyll, propyl paraben

Manufactured for: Dr. Knoll Products, Inc.
274 Weaver Street • P.O. Box 116 • Canby, OR 97001
TOLL FREE: 1-800-877-8434

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)	

HYPROMELLOSES (UNII: 3NXW29V3WO)
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)
ALOE VERA LEAF (UNII: ZY81Z83H0X)
LAVENDER OIL (UNII: ZBP1YXW0H8)
TEA TREE OIL (UNII: VIF565UC2G)
PICEA MARIANA LEAF OIL (UNII: Q1J49L1A5O)
ROSEMARY OIL (UNII: 8LGU7VM393)
SAGE OIL (UNII: U27K0H1H2O)
JUNIPER BERRY OIL (UNII: SZH16H44UY)
CAJUPUT OIL (UNII: J3TO6BUQ37)
PEPPERMINT OIL (UNII: AV092KU4JH)
HORSE CHESTNUT (UNII: 3C18L6RJAZ)
METHYL PARABEN (UNII: A2I8C7HI9T)
SODIUM COPPER CHLOROPHYLLIN (UNII: 1D276TYV9O)
PROPYL PARABEN (UNII: Z8IX2SC1OH)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
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 Nutraceuticals, Inc.		053760034	manufacture(50638-100)

Revised: 6/2012

Dr. Knoll Products, Inc.