CAMPHOR, MENTHOL - camphor, menthol ointment Active & Innovative 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.

DRUG FACTS

Active Ingredients (% by weight)

Camphor4.0% Menthol 4.0%

Purpose

Analgesic (pain relief)

Uses

For the temporary relief of minor aches and pains of muscles and joints associated with simple backache, arthritis, strains, bruises and sprains, etc.

Warnings

- For external use only.
- Avoid getting into eyes or on mucous membranes.
- If the conditions worsens, or if the symptoms persists for more than 7 days or clears up and occurs again within a few days, discontinue use of this product and consult a doctor.
- Do not apply to wounds or damaged skin. Do not bandage tightly.

OTC - Keep Out of Reach of Children Section

Keep out of reach of children.

Other Warnings

- Use only as directed.
- Do not use if pregnant or breastfeeding.
- If swallowed, get medical help or contact a poison Control center right away.

Directions

Adults and children 12 years of age or older: Rub this soothing cream on the affected area not more that 3 to 4 times daily.

Children under the age of 12: Do not use, consult a doctor.

Other Information

Store under normal storage conditions. Store away from Children.

Inactive Ingredients

Caprylyl glycol, cetyl alcohol, chondroitin sulphate, eucalyptus oil, glucosamine sulfate, glycerin, glycol stearate, grape seed oil, C13-14 isoparaffin, Laureth-7, lavender oil, methylsulfonyl-methane

(MSM), phenoxyethanol, polyacrylamide, polysorbate-20, sea cucumber extract, sorbic acid, stearyl alcohol, thymol, urea, Vitamin E (tocopheral acetate), water, wintergreen oil.

Questions?

Questions? 416-967-3746

Principal Display PanelPROFESSIONAL THERAPYMAXIMUM STRENGTH

MAXIMA POTENCIA

MuscleCare TM

PAIN RELIEVING OINTMENT/ POMADA ALIVIANTE DEL DOLOR

by / por el Dr. Chris Oswald

FOR MUSCLE & JOINT PAIN RELIEF

PARA EL ALIVIO DEL DOLOR MUSCULAR Y ARTICULAR

GREASELESS • STAINLESS • SHAKE WELL BEFORE EACH USE

SIN GRASA • NO MANCHA • AGITAR BIEN ANTES DE CADA USO

NET WT Peso NETO 115g. (4oz.)



MuscleCare OINTMENT LABEL - USA











DEC 16 2009

black

pantone 877 silver

pantone process blue 276 blue pantone 485 red

CAMPHOR, MENTHOL

camphor, menthol ointment

camphor, menthol ointment							
Product Information							
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:	50421-004		
Route of Administration	TOPICAL						
Active Ingredient/Active I	Aoiety						
In	gredient Name		Basis of St	rength	Strength		
CAMPHOR (UNII: 5TJD82A1ET) (0	CAMPHOR - UNII:5TJD82A1ET)	CAMPHOR		4.6 g in 115 g		
MENTHOL (UNII: L7T10EIP3A) (M	ENTHOL - UNII:L7T10EIP3A)		MENTHOL		4.6 g in 115 g		
Inactive Ingredients							
	Ingredient Nam	e			Strength		
CAPRYLYL GLYCOL (UNII: 00 Y	U5438U)						
CETYL ALCOHOL (UNII: 936JST	6JCN)						
EUCALYPTUS OIL (UNII: 2R04ONI662)							
GLUCOSAMINE SULFATE (UNII: 1FW7WLR731)							
GLYCERIN (UNII: PDC6A3C0OX)							
GLYCOL STEARATE (UNII: 0324	G66D0E)						
C13-14 ISOPARAFFIN (UNII: E4F12ROE70)							
LAVENDER OIL (UNII: ZBP1YXW)H8)						
DIMETHYL SULFONE (UNII: 9H4	PO4Z4FT)						
PHENOXYETHANOL (UNII: HIE49	2ZZ3T)						
POLYSORBATE 20 (UNII: 7T1F30	V5YH)						
SORBIC ACID (UNII: X045WJ989							
STEARYL ALCOHOL (UNII: 2KR89I4H1Y)							
THYMOL (UNII: 3J50XA376E)							
UREA (UNII: 8W8T17847W)							
.ALPHATO COPHEROL ACETATE, DL- (UNII: WR1WPI7EW8)							
WATER (UNII: 059QF0KO0R)							
METHYL SALICYLATE (UNII: LA	V5U5022Y)						
Packaging							
# Item Code	Package Description	Marketing Sta	art Date	Marketi	ing End Date		
1 NDC:50421-004-34 115 g	in 1 TUBE						
Marketing Informatio	n						
–	cation Number or Monogra	ph Citation Ma	rketing Start Da	ate Mar	keting End Date		
OTC monograph final part348	Ū		8/2010				

Labeler - Active & Innovative Inc. (206978079)

Establishment

Name	Address	ID/FEI	Business Operations
International Laboratories (Canada) Ltd.		2470 10 150	manufacture

Revised: 1/2010

Active & Innovative Inc.