REVALIFE- topical menthol ointment
International Nutraceutical Company of America (INCA), LLC

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 Ingredient : Menthol 3%

Purpose-Topical Analgesic

Uses-Temporarily relieves minor pain of joints and muscles associated with arthritis, bursitis, tendonitis, strains

Directions: Apply to clean, dry skin over painful joint or muscle gently massaging until cream disappears. For optimum results use daily for 30 days and continue to use daily thereafter. Repeat as neccessary. Close cap tightly after use.

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

For external use only. Do not bandage tightly or use with a heating pad. Avoid contact with mouth, eyes, and mucous membranes. Do not apply to wounds, damaged, broken, or irritated skin.

Stop use and ask a doctor if: Symptoms persists over 7 day or clear up and occur again within a few days. Redness is present or irritation develops. Using on a child 12 years of age or under.

Inactive Ingredients: EDTA, Ethanol, Isopropyl palmitate, Methyl Paraben, Monosodium Phosphate, N-Acetyl Glucosamine, Poloxamer 407, Propyl Paraben, Soy Lecithin, Todopherol Acetate (Vitamin E), Water

If pregnant or breast feeding, ask a health professional before use

REVALIFE

topical menthol ointment

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:42452-378
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	937.5 mg in 1 g

Inactive Ingredients	
Ingredient Name	**Strength**
ISOPROPYL PALMITATE (UNII: 8CRQ2TH63M)	
ALPHA-TOCOPHEROL (UNII: H4N855PNZ1)	
LECITHIN, SOYBEAN (UNII: 1DI56QDM62)	
ALCOHOL (UNII: 3K9958V90M)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
N-ACETYLGLUCOSAMINE (UNII: V956696549)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:42452-378-48	1 in 1 CARTON	01/26/2012	
1	NDC:42452-378-49	85 g in 1 TUBE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	01/26/2012	

Labeler - International Nutraceutical Company of America (INCA), LLC (941002250)

Registrant - International Nutraceutical Company of Americe (INCA), LLC (941002250)

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