## CELADRIN - menthol cream Natural Factors Nutritional Products Ltd

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.

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## **Active Ingredient**

Menthol 1.5%

## Purpose

Pain relieving cream

#### Use

Temporarily relieves minor aches and pains of muscles and joints associated with: simple backache arthritis strains bruises sprains

## Warnings

For external use only

#### Do not use

on wounds or damaged skin

### When using this product

- avoid contact with eyes or mucous membranes
- do not bandage tightly

### Stop use and ask a doctor if

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

## Keep out of reach of children

#### **Directions**

- Adult and children 2 years of age and older: Apply to affected area not more than 3 to 4 times daily.
- Children under 2 years of age: consult a physician.

## **Inactive Ingredients**

aloe vera gel, celadrin® proprietary blend of esterified fatty acids (7.5%), cetyl alcohol, cinnamon oil, eucalyptus oil, glyceryl stearate, grape seed oil, hypromellose, jojoba oil, peppermint oil, potassium

sorbate, purified water, squalane, stearic acid, stearyl alcohol, tea tree oil, vegetable glycerin, wintergreen oil.

Image of the principal display panel



# **CELADRIN**°

## Muscle & Joint Pain Relieving Cream



## Provides Penetrating Pain Relief Absorbent and Non-greasy

Net Wt. 2 oz. (57 g)

### **CELADRIN**

menthol cream

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Product Type HUMAN OTC DRUG Item Code (Source) NDC:31586-2683

Route of Administration TOPICAL

## **Active Ingredient/Active Moiety**

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1	Ingredient Name	Basis of Strength	Strength
MENTHOL (UNII: L7T10EIP3A)	(MENTHOL - UNII:L7T10EIP3A)	MENTHOL	1.5 g in 100 g

Inactive Ingredients						
Ingredient Name	Strength					
ALOE VERA LEAF (UNII: ZY81Z83H0X)						
CETYL ALCOHOL (UNII: 936JST6JCN)						
CINNAMON OIL (UNII: E5GY4I6 YCZ)						
EUCALYPTUS OIL (UNII: 2R04ONI662)						
GLYCERYL MONOSTEARATE (UNII: 230 O U9 XXE4)						
HYPROMELLOSE (UNII: 3NXW29V3WO)						
PEPPERMINT OIL (UNII: AV092KU4JH)						
POTASSIUM SORBATE (UNII: 1VPU26JZZ4)						
WATER (UNII: 059QF0KO0R)						
SQUALANE (UNII: GW89575KF9)						
STEARIC ACID (UNII: 4ELV7Z65AP)						
STEARYL ALCOHOL (UNII: 2KR89I4H1Y)						
GLYCERIN (UNII: PDC6A3C0OX)						
GRAPE SEED OIL (UNII: 930 MLC8 XGG)						
JOJOBA OIL (UNII: 724GKU717M)						
TEA TREE OIL (UNII: VIF565UC2G)						
METHYL SALICYLATE (UNII: LAV5U5022Y)						
CETYL ESTERS WAX (UNII: D072FFP9GU)						

Packaging									
# Item Code	Package Description	Marketing Start Date	Marketing End Date						
1 NDC:31586-2683-1	57 g in 1 TUBE								

Marketing Information									
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date						
OTC monograph not final	part348	04/30/2007							

## Labeler - Natural Factors Nutritional Products Ltd (205628329)

Establishment								
Name	Address	ID/FEI	Business Operations					
Natural Factors Nutritional Products Ltd		205628329	manufacture					

Revised: 4/2010