ARTHRI-ZEN RELIEF - menthol cream RZN Nutraceuticals, 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

Menthol 5%

Purpose

Menthol 5%......Topical Analgesic

Uses

For the temporary relief of minor aches and pains associated with arthritis, backaches, sprains, bruises, strains, and stiffness.

Warnings

- For external use only.
- Use only as directed.
- Avoid contact with eyes and mucous membranes.

Do not apply to open wounds or damaged skin.

KEEP OUT OF REACH OF CHILDREN

- if swallowed get medical help or contact a poison center right away.
- Do not bandage tightly or use with heating pads.

Consult a physician before use for children under 12 or if; pregnant or nursing; condition persists more than seven days or condition clears up and returns within seven days; excessive skin irritation occurs; you are prone to allergic reactions to salicylates, including aspirin.

Directions

- Adults and children under 12 years of age and older: apply to affected area no more than 3 to 4 times daily.
- Children under 12: consult a physician.
- Apply generously and massage into affected areas until completely absorbed.
- Apply before and after sports or exercise to help soothe aching muscles, muscle strain, and stiffness.

Repeat as needed up to four times a day.

Other Information

Inactive Ingredients

Water, Methyl Glucose Sesquistearate, Arthri-Zen Relief Proprietary Herbal Extract Blend, Natural Oil of Wintergreen (Gaultheria procumbens), Avocado Oil (Persea gratissima), Stearic Acid, Aloe

(Aloe barbadensis), Grape Seed Oil (Vitis vinifera), Cyclomethicone, Shea Butter (Butyrospermum parkii),

Steareth-10, Phenoxyethanol, Ceteareth-20, Steareth-2.

Questions or comments?

1-800-226-7031 or info@rznnutra.com

This product is manufactured exclusively for: RZN Nutraceuticals, Inc. Miami, FL 33186

- Soothing and medicated analgesic rub for aching joints and muscles
- Effective for pre-exercise warm-up
- Deep penetrating therapeutic pain relief
- With skin moisturizing conditioners aloe, shea butter, avocado, and grape seed oil
- Contains Arthri-Zen Relief's clinically tested herbal formula

Principal Display Panel

Fast and Long Lasting
Pain Relief
Arthri Zen
RELIEF CREAM

Temporary Relief of Minor Aches and Pains Associated with Arthritis, Backaches, Sprains, Bruises, Strains, and Stiffness.

Net wt 3.0 oz.(85g)



Tempory Relief of Minor Aches and Pains Associated with Arthritis, Backaches, Sprains, Bruises, Strains, and Stiffness. Net wt 3.0 oz. (85q)

- Soothing and medicated analgesic rub for aching joints and muscles
- Effective for pre-exercise warm-up
- Deep penetrating therapeutic pain relief . Contains Arthri-Zen Relief's
- · With skin moisturizing conditioners aloe, shea butter, avocado, and grape seed oil
- clinically tested herbal formula

Drug Facts

Active Ingredients

Purpose

Uses For the temporary relief of minor aches and pains associated with arthritis, backaches, sprains, bruises, strains, and stiffness.

- For external use only.
- Use only as directed.
- Avoid contact with eyes and mucous membrane.
- Do not apply to open wounds or damaged skin.
 KEEP OUT OF REACH OF CHILDREN—if swallowed get medical help or contact a poison center right away.
- Do not bandage tightly or use heating pads.
 Consult a physician before use for children under 12 or if: pregnant or nursing; condition persists more than seven days or condition clears up and returns within seven days; excessive skin imitation occurs; you are prone to allergic reactions to salicylates, including aspirin.

- Adults and children 12 years of age and older: apply to affected area no more than 3 to 4 times daily.
- Children under 12: consult a physician.
- Apply generously and massage into affected areas until completely absorbed.
- Apply before and after sports or exercise to help soothe aching muscles, muscle strain, and stiffness. Repeat as needed up to four times per day.

Other Information Store at 20° to 25°C (68° to 77°F)

Inactive Ingredients Water, Methyl Glucose Sesquistearate, Arthri-Zen Relief Proprietary Herbal Extract Blend, Natural Oil of Wintergreen (Gauttheria procumbens), Avocado Oil (Persea gratissima), Stearic Acid, Aloe (Aloe barbadensis), Grape Seed Oil (Vitis vinifera), Cyclomethicone, Shea Butter (Butyrospermum parkii), Steareth-10, Phenoxyethanol, Ceteareth-20, Steareth-2.

Questions or comments? 1-800-226-7031 or info@rznnutra.com

This product is manufactured exclusively for: RZN Nutraceuticals, Inc. Miami, FL 33186



ARTHRI-ZEN RELIEF

menthol cream

Droduct	Information
Product	information

HUMAN OTC DRUG Product Type Item Code (Source) NDC:34876-001

TOPICAL Route of Administration

Active Ingredient/Active Moiety

Ingredient Name Basis of Strength Strength

MENTHOL (UNII: L7T10 EIP3A) (MENTHOL - UNII:L7T10 EIP3A	MENTHOL 5	5 g in 100
---	-----------	------------

Inactive Ingredients		
Ingredient Name	Strength	
WATER (UNII: 059QF0KO0R)		
GAULTHERIA PROCUMBENS TOP (UNII: 830295X963)		
AVO CADO O IL (UNII: 6 VNO 72 PFC 1)		
STEARIC ACID (UNII: 4ELV7Z65AP)		
ALOE VERA LEAF (UNII: ZY8 1Z8 3H0 X)		
GRAPE SEED OIL (UNII: 930 MLC8 XGG)		
CYCLOMETHICONE (UNII: NMQ347994Z)		
SHEA BUTTER (UNII: K49155WL9Y)		
STEARETH-10 (UNII: FD0913P475)		
PHENO XYETHANO L (UNII: HIE492ZZ3T)		
POLYOXYL 20 CETOSTEARYL ETHER (UNII: YRC528SWUY)		
STEARETH-2 (UNII: V56DFE46J5)		

P	ackaging			
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:34876-001-24	85 g in 1 TUBE		

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	05/01/2007	

Labeler - RZN Nutraceuticals, Inc. (019943765)

Establishment				
Name	Address	ID/FEI	Business Operations	
Accupack Midwest		139637433	manufacture(34876-001)	

Revised: 12/2013 RZN Nutraceuticals, Inc.