

**AT ONE WITH NATURE- menthol 1% gel, dentifrice
BIOCARE LABS 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.

At One with nature Root Revitalizer for Dry Itchy Scalp

ACTIVE INGREDIENT

Menthol 1.00%

PURPOSE

Topical Analgesic

USE

temporary relief of itching associated with scalp irritation.

WARNINGS

- for external use only

When using this product

- avoid contact with eyes. If contact occurs rinse eyes thoroughly with water.

Stop use and ask a doctor if

- condition worsens, or if symptoms persist for more than 7 days
- symptoms clear up and occur again within a few days.
- excessive skin irritation

Keep out of reach of children.

If swallowed, get medical help or contact a Poison Control Center immediately.

Directions

- Adult & children 2 year of age & older. Part hair into section & apply a dime size amount sparingly.
- Massage into scalp to invigorate and insure absorption.
- Apply to affected area not more then 3 to 4 times daily. Use daily for maximum results or flaking & itching has stopped.
- Children under 2 years of age ask a doctor

INACTIVE INGREDIENTS

Petrolatum, Helianthus Annuus (Sunflower) Seed Oil, Ricinus Communis (Castor) Seed Oil, Salicylic Acid, Polyethylene, Paraffin, Propylene Glycol, Water, Calendula Officinalis (Pot Marigold) Flower Extract, Anthemis Nobilis Chamomile Flower Extract, Tilia Cordata (Linden) Flower Extract, Centaurea Cyanus (Cornflower) Flower Extract, Chamomilla Recutita (Matricaria) Flower Extract, Hypericum Perforatum Extract (St. John's Wort) Extract, Fragrance, Olea Europaea (Olive) Fruit Oil, Sulfur, Sesame (Sesamum Indicum) Oil, Tocopheryl Acetate, BHT, Propylparaben, Green 6, Yellow 11

PRINCIPAL DISPLAY PANEL

biocare5oz

At One with nature
Sunflower Oil
ROOT REVITALIZER
For Dry, Itchy Scalp
Revitalisant Des Racines

154g (5.5 Oz.)

ROOT REVITALIZER gives quick relief from itching and flaking while clinically proven ingredients immediately help restore your natural moisture balance and relieve itching and flaking associated with dry scalp and dandruff conditions.

Drug Facts
Active Ingredient Menthol 1%
Purpose Topical Anesthetic

Use: • temporary relief from itching associated with scalp irritation.
Warnings: • For external use only
 When using this product: • Avoid contact with eyes. If contact occurs, rinse eyes thoroughly with water.
Stop use & ask a doctor if: • condition worsens or symptoms persist for more than 7 days
 • symptoms clear up and occur again within a few days • excessive skin irritation occurs.
 Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center immediately.

Directions: • Adults & children 2 years of age & older: Part hair into sections & apply a dime size amount sparingly. • Massage into scalp to invigorate and insure absorption. • Apply to affected area no more than 3 to 4 times daily. Use daily for maximum results or until flaking & itching has stopped. • Children under 2 years of age, ask a doctor.

Inactive Ingredients: Petrolatum, Helianthus Annuus (Sunflower) Seed Oil, Ricinus Communis (Castor) Seed Oil, Salicylic Acid, Polyethylene, Paraffin, Propylene Glycol, Water, Calendula Officinalis (Pot Marigold) Flower Extract, Anthemis Nobile (Chamomile) Flower Extract, Tilia Cordata (Linden) Flower Extract, Centaurea Cyanus (Cornflower) Flower Extract, Chamomilla Recutita (Matricaria) Flower Extract, Hypericum Perforatum (St. John's Wort) Flower/Leaf/Stem Extract, Fragrance, Olea Europaea (Olive) Fruit Oil, Sulfur, Sesame (Sesamum Indicum) Oil, Tocopheryl Acetate, BHT, Propylparaben, Green 6, Yellow 11

LE REVITALISANT DES RACINES, apaise rapidement les démangeaisons et élimine les pellicules par l'infusion d'huiles et de conditionneuses de haute qualité. Des ingrédients, soigneusement testés, aident immédiatement à rétablir une hydratation équilibrée, calme les démangeaisons et élimine les pellicules associées aux conditions du cuir chevelu sec. **Applications:** 1) Séchez les cheveux par section et appliquez une petite quantité rose par rose. 2) Massez dans le cuir chevelu pour l'envoyer et faire pénétrer. 3) Appliquez sur cuir chevelu au moins deux fois par semaine. Utilisez chaque jour pour un résultat maximum jusqu'à la disparition des démangeaisons et pellicules.
ATTENTION: In cas de contact avec les yeux, rincez abondamment avec de l'eau. **TENIR HORS DE PORTEE DES ENFANTS.**

Made in U.S.A.
BIOCARE LABS
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AT ONE WITH NATURE

menthol 1% gel, dentifrice

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:54602-011
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Menthol (UNII: L7T10EIP3A) (Menthol - UNII:L7T10EIP3A)	Menthol	10 mg in 1 g

Inactive Ingredients

Ingredient Name	Strength
PETROLATUM (UNII: 4T6H12BN9U)	
SUNFLOWER OIL (UNII: 3W1JG795YI)	
CASTOR OIL (UNII: D5340Y2I9G)	
SALICYLIC ACID (UNII: O414PZ4LPZ)	
HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7)	
PARAFFIN (UNII: I9O0E3H2ZE)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0K00R)	
CALENDULA OFFICINALIS FLOWER (UNII: P0M7O4Y7YD)	
CHAMAEMELUM NOBILE FLOWER (UNII: O2T154T6OG)	
TILIA CORDATA FLOWER (UNII: CFN6G1F6YK)	
CENTAUREA CYANUS FLOWER (UNII: QZ239038YC)	
CHAMOMILE (UNII: FGL3685T2X)	
HYPERICUM PERFORATUM (UNII: XK4IUX8MNB)	
OLIVE OIL (UNII: 6UYK2W1W1E)	
SULFUR (UNII: 70FD1KFU70)	
SESAME OIL (UNII: QX10HYY4QV)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
BUTYLATED HYDROXYTOLUENE (UNII: 1P9D0Z171K)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
D&C GREEN NO. 6 (UNII: 4QP5U84YF7)	
D&C YELLOW NO. 11 (UNII: 44F3HYL954)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:54602-011-05	154 g in 1 CANISTER	09/18/2014	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	09/18/2014	

Labeler - BIOCARE LABS INC. (798953493)

Establishment

Name	Address	ID/FEI	Business Operations
RNA PHARMA, LLC		079103999	manufacture(54602-011)

Revised: 11/2014

BIOCARE LABS INC.