

**PERIOSCIENCES WHITE CARE AO PRO- sodium fluoride paste, dentifrice  
PERIOSCIENCES 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.*

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**PERIOSCIENCES White Care AO Pro Toothpaste**

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**Active ingredient**

Sodium fluoride 0.24%  
(0.15% w/v fluoride ion)

**Purpose**

Anticavity

**Uses**

Aids in prevention of dental cavities.

**Warning**

**Keep out of reach of children under 2 years of age.**

If more than used for brushing is accidentally swallowed, get medical help or contact a Poison Control Center right away.

**Directions**

- Adults and children 2 years of age and older: Brush teeth thoroughly, preferably after each meal or at least twice a day, or as directed by a dentist or doctor. Instruct children under 6 years of age in good brushing and rinsing habits (to minimize swallowing). Supervise children as necessary until capable of using without supervision.
- Children under 2 years of age: Ask a dentist or physician

**Other information**

Not intended for ingestion. Upon application in the mouth, if you experience any irritation or unusual sensitivity, discontinue and consult your dental professional.

## **Inactive ingredients**

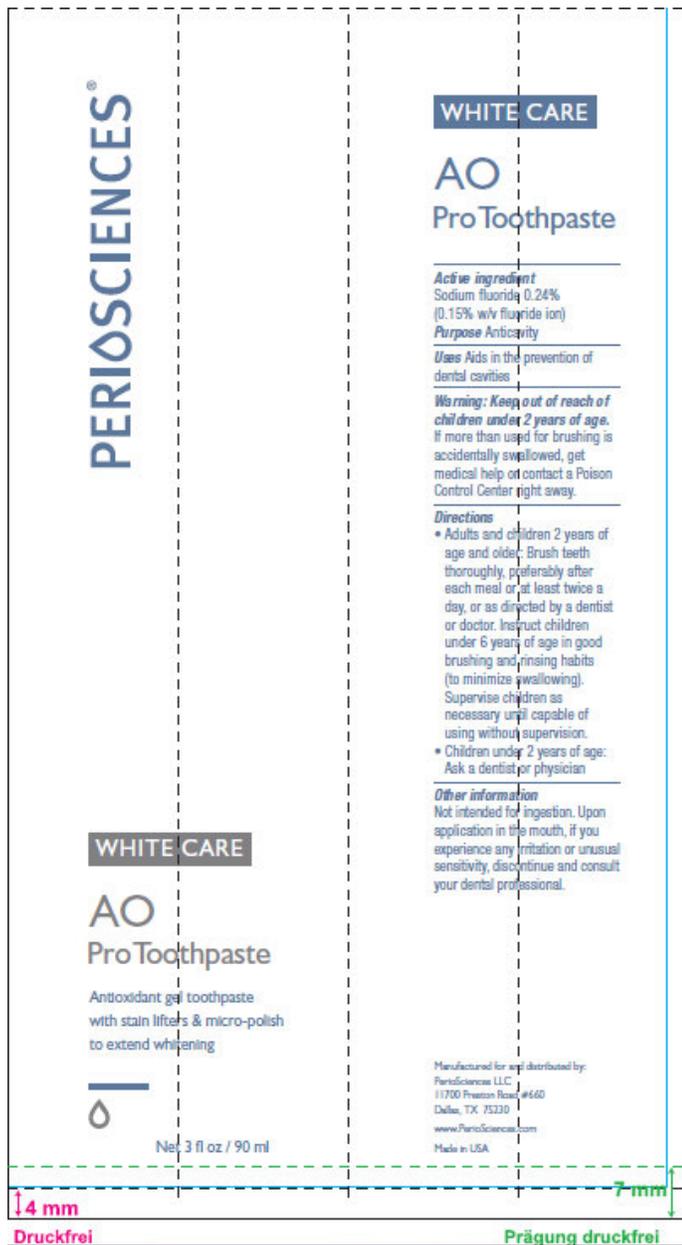
glycerin, aqua (water), hydrated silica, sorbitol, propylene glycol, sodium methyl cocoyl taurate, pvp, hydroxyapatite, cocamidopropyl betaine, ferulic acid, phloretin, hesperetin, menthol, mentha piperita (peppermint) oil, sodium ascorbyl phosphate, sodium olivoyl glutamate, citrus grandis (grapefruit) fruit extract, stevia rebaudiana bertonii, sodium citrate, ethylhexylglycerin, cellulose gum, potassium sorbate, titanium dioxide, phenoxyethanol, sodium polyphosphate, caprylyl glycol

## **Questions or Comments?**

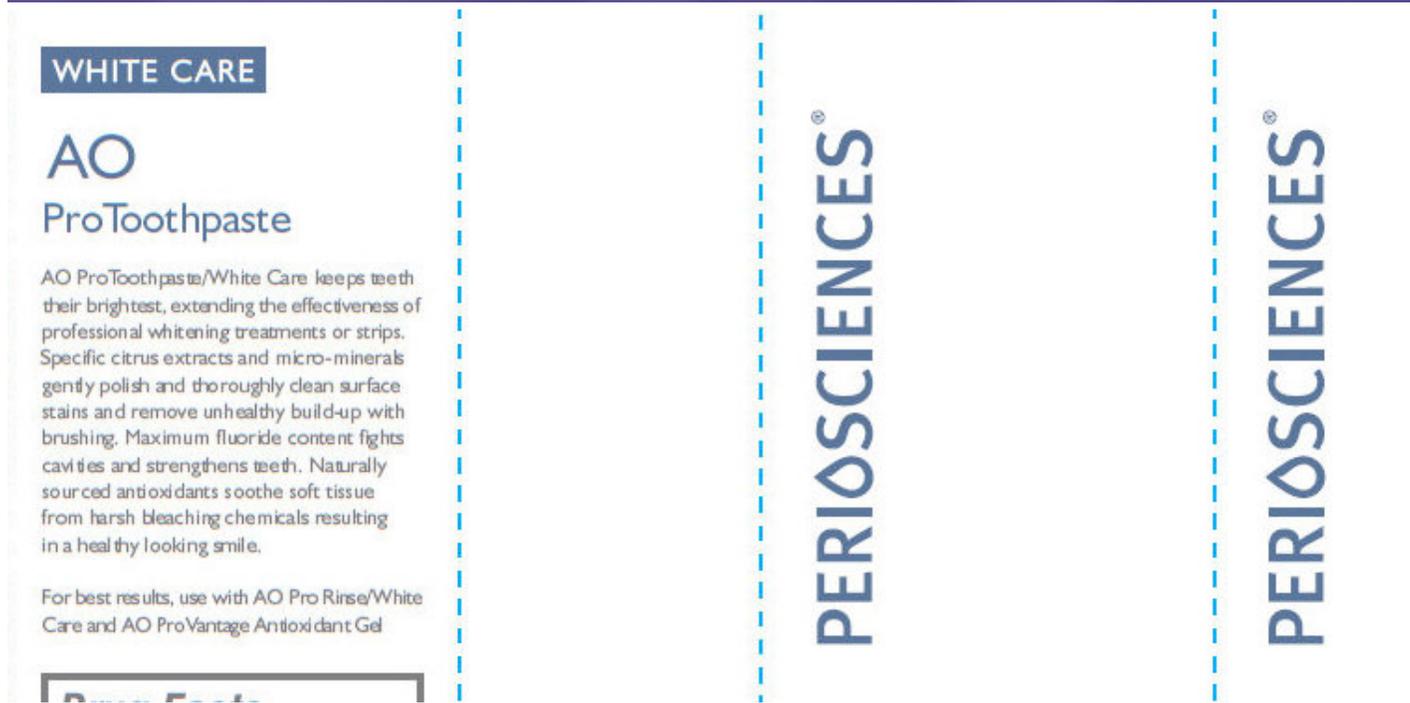
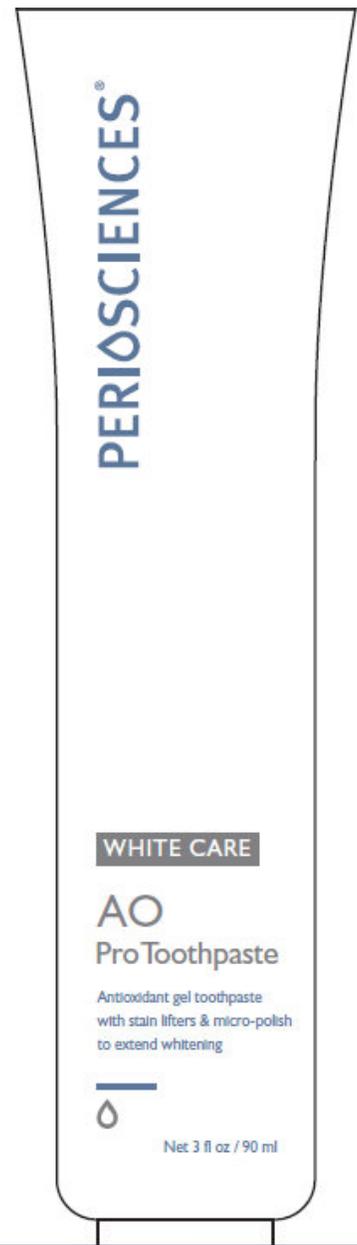
Call toll-free 1-800-915-8110

PERIOSCIENCES WHITE CARE AO Pro Toothpaste Antioxidant gel toothpaste with stain lifters and micro-polish to extend whitening Net 3 fl oz / 90 ml Manufactured for and distributed by: PerioSciences LLC 11700 Preston Road #660 Dallas, TX 75230 [www.PerioSciences.com](http://www.PerioSciences.com) Made in USA

**PERIOSCIENCES White Care AO Pro Toothpaste 90ml (53238-001-90)**



Tuben-Höhe: 176 mm  
 Longeur du tube: 176 mm  
 Length of tube shoulder to end of tube: 176 mm



**Drug Facts**

Active ingredient	Purpose
Sodium fluoride 0.24% (0.15% w/v fluoride ion)	Anti-cavity

**Uses** Aids in the prevention of dental cavities

**Warning**  
Keep out of reach of children under 2 years of age. If more than used for brushing is accidentally swallowed, get medical help or contact a Poison Control Center right away.

**Directions**  
• Adults and children 2 years of age and older: Brush teeth thoroughly, preferably after each meal or at least twice a day, or as directed by a dentist or doctor. Instruct children under 6 years of age in good brushing and rinsing habits (to minimize swallowing). Supervise children as necessary until capable of using without supervision. • Children under 2 years of age: Ask a dentist or physician

**Other information**  
Not intended for ingestion. Upon application in the mouth, if you experience any irritation or unusual sensitivity, discontinue and consult your dental professional.

**Inactive ingredients**  
glycerin, aqua (water), hydrated silica, sorbitol, propylene glycol, sodium methyl cocoyl taurate, pvp, hydroxyapatite, cocamidopropyl betaine, ferulic acid, phloretin, hesperetin, menthol, mentha piperita (peppermint) oil, sodium ascorbyl phosphate, sodium di-voyl glutamate, citrus grandis (grapefruit) fruit extract, stevia rebaudiana bertoni, sodium citrate, ethylhexylglycerin, cellulose gum, potassium sorbate, titanium dioxide, phenoxyethanol, sodium polyphosphate, caprylyl glycol

**Questions or Comments?**  
Call toll-free 1-800-915-8110

Manufactured for and distributed by:  
PerioSciences LLC  
11700 Preston Road #660  
Dallas, TX 75230  
www.PerioSciences.com - Made in USA



**PERIOSCIENCES WHITE CARE AO PRO**

sodium fluoride paste, dentifrice

Product Information			
<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:53238-001
<b>Route of Administration</b>	DENTAL		
Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
<b>SODIUM FLUORIDE</b> (UNII: 8ZYQ1474W7) (FLUORIDE ION - UNII:Q80VPU4080)	SODIUM FLUORIDE	0.24 mg in 100 mL	

## Inactive Ingredients

Ingredient Name	Strength
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>HYDRATED SILICA</b> (UNII: Y6O7T4G8P9)	
<b>SORBITOL</b> (UNII: 506T60A25R)	
<b>PROPYLENE GLYCOL</b> (UNII: 6DC9Q167V3)	
<b>SODIUM METHYL COCOYL TAURATE</b> (UNII: JVL98CG53G)	
<b>TRIBASIC CALCIUM PHOSPHATE</b> (UNII: 91D9GV0Z28)	
<b>COCAMIDOPROPYL BETAINE</b> (UNII: 5OCF3O11KX)	
<b>FERULIC ACID</b> (UNII: AVM951ZWST)	
<b>PHLORETIN</b> (UNII: S5J5OE47MK)	
<b>HESPERETIN</b> (UNII: Q9Q3D557F1)	
<b>MENTHOL</b> (UNII: L7T10EIP3A)	
<b>PEPPERMINT OIL</b> (UNII: AV092KU4JH)	
<b>SODIUM ASCORBYL PHOSPHATE</b> (UNII: 836SJG51DR)	
<b>PUMMELO</b> (UNII: ET1TN5W71X)	
<b>STEVIA REBAUDIANA WHOLE</b> (UNII: 6U422Y08O2)	
<b>SODIUM CITRATE</b> (UNII: 1Q73Q2JULR)	
<b>ETHYLHEXYLGLYCERIN</b> (UNII: 147D247K3P)	
<b>CARBOXYMETHYLCELLULOSE SODIUM</b> (UNII: K679OBS311)	
<b>POTASSIUM SORBATE</b> (UNII: 1VPU26JZZ4)	
<b>TITANIUM DIOXIDE</b> (UNII: 15FIX9V2JP)	
<b>PHENOXYETHANOL</b> (UNII: HIE492ZZ3T)	
<b>SODIUM POLYMETAPHOSPHATE</b> (UNII: P1BM4ZH95L)	
<b>CAPRYLYL GLYCOL</b> (UNII: 00YIU5438U)	

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:53238-001-90	1 in 1 CARTON	09/13/2012	
1		90 mL 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 final	part355	09/13/2012	

**Labeler** - PERIOSCIENCES LLC (961798605)

## Establishment

Name	Address	ID/FEI	Business Operations
Chemolee Lab Corp		809982754	manufacture(53238-001)

