

**TANDA PEARL PROFESSIONAL WHITENING- sodium fluoride paste, dentifrice**  
**Syneron Beauty 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.*

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**Tanda pearl™ professional whitening toothpaste**

**Drug Facts**

**Active Ingredients**

Sodium Fluoride 0.25% w/w

**Purpose**

anticavity

**Uses**

Aids in prevention of dental decay

**Warning**

**Keep out of reach of children under 6 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: Consult a dentist or doctor.

**Inactive Ingredients**

Glycerin, Water (Aqua), Silica, Sorbitol, Xylitol, Flavor (Aroma), Poloxamer, Sodium Lauryl Sulfate, Carbomer, FD&C Blue #1 (CI 42090), Sodium Benzoate, Sodium Hydroxide, Sparkle (CI 77019, CI 77891), Sucralose, and Xanthan Gum.

Distributed by Syneron Beauty Inc., 11-380 Jamieson Parkway, Cambridge, ON, N3C 4N4

Manufactured by Ultradent Products, Inc. South Jordan, Utah 84095, USA.

**PRINCIPAL DISPLAY PANEL - 133g Tube Carton**

**TANDA**

**pearl™**

professional whitening  
toothpaste

NET WT 4.7 oz • 133g

Cool mint with fluoride

<b>Drug Facts</b>	<b>Drug Facts (cont.)</b>
<b>Active Ingredients (Purpose)</b> Sodium Fluoride 0.25% w/w (anticaavity)	<b>Directions:</b> • 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: Consult a dentist or doctor.
<b>Uses:</b> Aids in prevention of dental decay	<b>Inactive Ingredients:</b> Glycine, Water (Aqua), Silica, Sorbitol, Xylitol, Flavor (Aroma), Poloxamer, Sodium Lauryl Sulfate, Carbomer, FD&C Blue #1 (CI 42090), Sodium Benzoate, Sodium Hydroxide, Sparkle (CI 77019, CI 77891), Sucralose, and Xanthan Gum.
<b>Warnings:</b> Keep out of reach of children under 6 years of age. If more than used for brushing is accidentally swallowed, get medical help or contact a Poison Control Center right away.	<b>Made in USA</b>

TANDA

pearl™

professional whitening  
toothpaste

**Maintain your Tanda Pearl results:**  
Specially formulated to maintain your whitest smile when used with the Tanda Pearl ionic teeth whitening system

**Professional whitening:**  
Removes surface stains to reveal whiter, brighter teeth every day

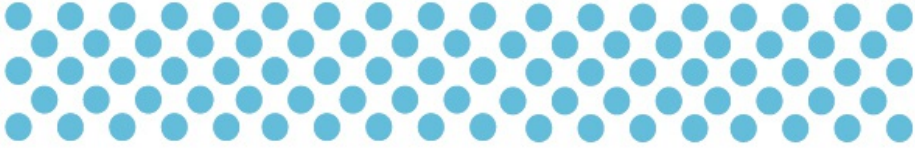
**Enamel-safe:**  
Whitens teeth quickly and safely while protecting enamel and preventing cavities

**Clean, minty fresh feeling:**  
Refreshing gel formula cleans and polishes teeth for fresher breath

TANDA

pearl™

professional whitening  
toothpaste



NET WT 4.7 oz • 133g

Cool mint with fluoride

<b>TANDA PEARL PROFESSIONAL WHITENING</b> sodium fluoride paste, dentifrice			
<b>Product Information</b>			
<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:46437-001
<b>Route of Administration</b>	DENTAL		

**Active Ingredient/Active Moiety**

Ingredient Name	Basis of Strength	Strength
Sodium Fluoride (UNII: 8ZYQ1474W7) (Fluoride ion - UNII:Q80VPU408O)	Sodium Fluoride	0.33 g in 133 g

**Inactive Ingredients**

Ingredient Name	Strength
Glycerin (UNII: PDC6A3C0OX)	
Water (UNII: 059QF0K00R)	
Silicon Dioxide (UNII: ETJ7Z6XBU4)	
Sorbitol (UNII: 506T60A25R)	
Xylitol (UNII: VCQ006KQ1E)	
Methyl Salicylate (UNII: LAV5U5022Y)	
Sodium Lauryl Sulfate (UNII: 368GB5141J)	
FD&C Blue NO. 1 (UNII: H3R47K3TBD)	
Sodium Benzoate (UNII: OJ245FE5EU)	
Sodium Hydroxide (UNII: 55X04QC32I)	
Sucralose (UNII: 96K6UQ3ZD4)	
Xanthan Gum (UNII: TTV12P4NEE)	

**Product Characteristics**

Color	BLUE	Score	
Shape		Size	
Flavor	MINT	Imprint Code	
Contains			

**Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:46437-001-01	1 in 1 BOX		
1		133 g in 1 TUBE		

**Marketing Information**

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL	part355	08/03/2012	

**Labeler** - Syneron Beauty Inc. (248047115)

Revised: 8/2012

Syneron Beauty Inc.