PERIOGEL- hydrogen peroxide gel
QNT Anderson, 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.

Periogel®

Drug Facts

Active ingredient

Hydrogen peroxide 1.7% (w/w)

Purpose

Oral Debriding Agent/Oral Wound Cleanser

Approved Uses

For temporary use in cleansing minor wounds or minor gum inflammation resulting from minor dental procedures, dentures, orthodontic appliances, accidental injury, or other irritations of the mouth and gums.

Warnings

Do not use for more than 7 days unless directed by a dentist or doctor. Spit out excess medication.

Stop use and ask a doctor if
- sore mouth symptoms do not improve in 7 days
- irritation, pain or redness persists or worsens;
- swelling, rash or fever develops.

Keep out of reach of children.

Directions for adults and children 2 years of age and older
- Apply several drops to the affected area of the mouth.
- Allow medication to remain in place at least 1 minute and then spit out.
- Use up to 4 times daily after meals and at bedtime or as directed by a dentist or doctor.
- Children under 12 years of age should be supervised in the use of this product.
- Children under 2 years of age:
  Consult a dentist or doctor.

Other information

Store at controlled room temperature (68°-77°F) in a cool, dry place away from direct sunlight.

Inactive ingredients

Inactive ingredients: ethyl alcohol (5% w/w), menthol, methyl salicylate, phosphoric acid, poloxamer 407, polysorbate 20, potassium sorbate, sodium saccharin, sorbitol, water.

Questions or comments?

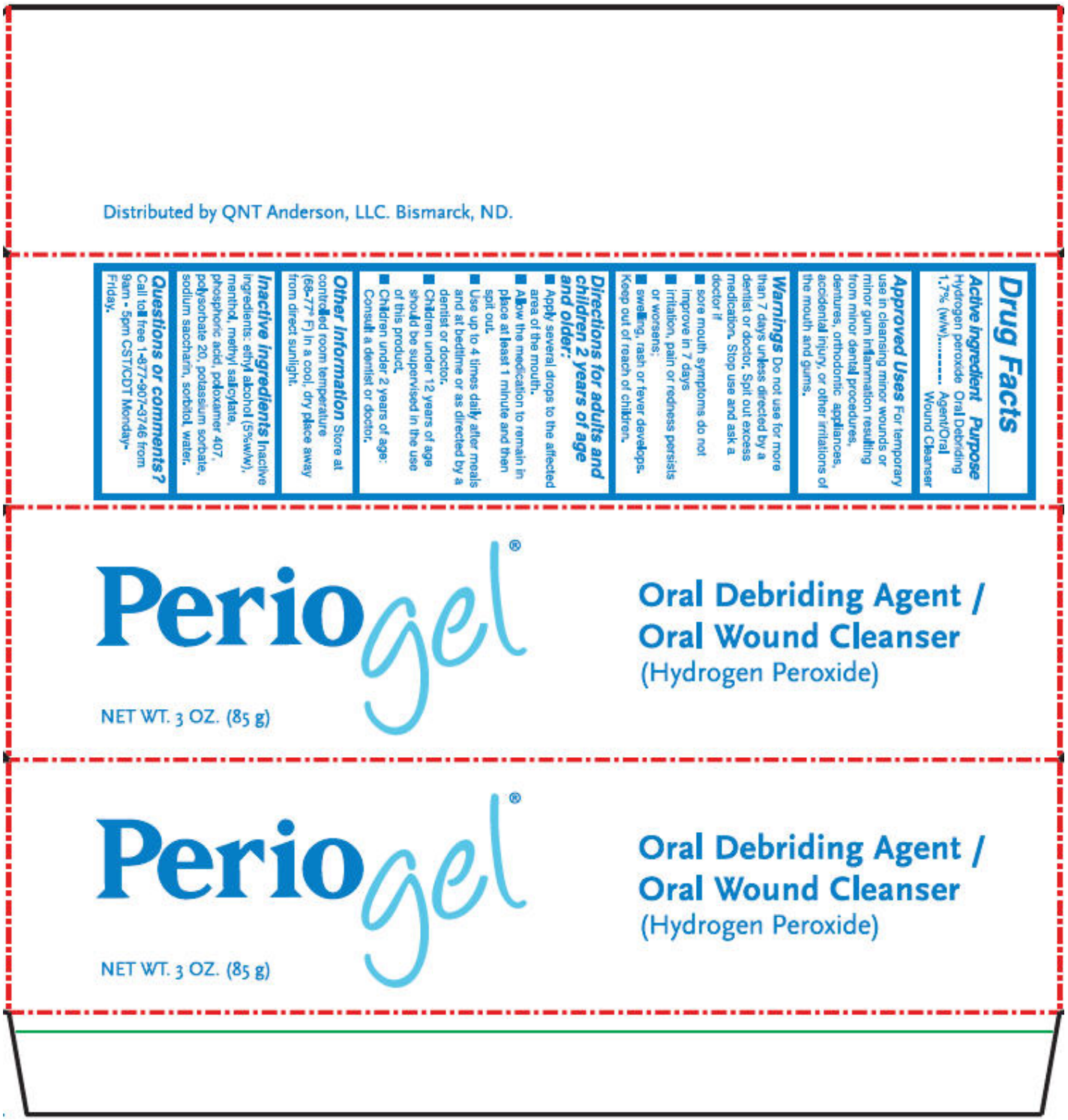
Call toll free 1-877-907-3746 from 9am - 5pm CST/CDT Monday-Friday.

PRINCIPAL DISPLAY PANEL - 85 g Tube Carton

Perio*gel*®

Oral Debriding Agent /
Oral Wound Cleanser
(Hydrogen Peroxide)

NET WT. 3 OZ. (85 g)



PERIOGEL

hydrogen peroxide gel

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:75908-017
Route of Administration	DENTAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
hydrogen peroxide (UNII: BBX060AN9V) (hydrogen peroxide - UNII:BBX060AN9V)	hydrogen peroxide	17 mg in 1 g

Inactive Ingredients

Ingredient Name	Strength
alcohol (UNII: 3K9958V90M)	50 mg in 1 g
menthol, unspecified form (UNII: L7T10EIP3A)	
methyl salicylate (UNII: LAV5U5022Y)	
phosphoric acid (UNII: E4GA8884NN)	
poloxamer 407 (UNII: TUF2IVW3M2)	
polysorbate 20 (UNII: 7T1F30V5YH)	
potassium sorbate (UNII: 1VPU26JZZ4)	
saccharin sodium (UNII: SB8ZUX40TY)	
sorbitol (UNII: 506T60A25R)	
water (UNII: 059QF0KO0R)	

Product Characteristics

Color		**Score**	
Shape		**Size**	
Flavor	WINTERGREEN	**Imprint Code**	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:75908-017-85	1 in 1 CARTON	04/01/2011	
1		85 g in 1 TUBE; Type 0: Not a Combination Product		
2	NDC:75908-017-28	1 in 1 CARTON	04/01/2011	
2		28.3 g 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 not final	part356	04/01/2011	

Labeler - QNT Anderson, LLC (962173030)

Establishment

Name	Address	ID/FEI	Business Operations
Unicep Packaging, Inc.		790263909	MANUFACTURE(75908-017)

Revised: 5/2022

QNT Anderson, LLC