PERIORESTORE- hydrogen peroxide gel DEN-MAT HOLDINGS, LLC.

PerioRestore

Active Ingredients

Hydrogen Peroxide

1.7% w/w

Purpose

Wound Cleanser

Indications & Uses

For temporary use in cleansing minor wounds and retreatment of inflammation resulting from dental procedures, or other irritations of the mouth and gums. Perio Restore may be used for lessening the presence of plaque, a known factor in development of gingivitis.

Warnings

Do not use Perio Restore Gel for more than 7 days unless directed by your dentist or physician. Stop use and ask your dentist or physician if:

- Symptoms of wounds or inflammation do not improve within 7 days.
- Irritation, pain or redness persists or worsens
- Swelling, rash or fever develops

Keep out of reach of children.

Children under 12 years of age should be supervised when using this product.

Directions

For children under 2 years of age, consult dentist or physician.

For adults and children 2 years of age and older:

- 1. Apply several drops of gel directly onto the affected area in the mouth.
- 2. Leave the material on the affected area for at least 60 seconds, then spit.
- 3. Use up to 4 times daily after meals and or a bedtime, or as directed by a dentist or physician.

Other Information

Store at a controlled room temperature, 25-25° C (68-77° F) and away from direct sunlight.

For your protection, do not use if tamper seal on box is broken or missing.

Inactive Ingredients

Ethyl Alcohol, Menthol, Methyl Salicylate, Phosphoric Acid, Poloxamer 407, Polysorbate 20, Potassium Sorbate, Sodium Saccharin, Sorbitol, Water.

Principal Display Panel

PerioRestore™

Oral Cleaning Gel

Clean Mint

1.7% Hydrogen Peroxide

Net Wt. 3 oz. (85 g)



Principal Display Panel

 $\textbf{PerioRestor} \, \mathbb{R}$

Oral Cleansing Gel

1.7% Hydrogen Peroxide

Net Wt. 3 oz. (85 g) Clean Mint

NDC 59883-018-87



PERIORESTORE

hydrogen peroxide gel

Product Information

Product Type HUMAN OTC DRUG Item Code (Source) NDC:59883-018

Route of Administration DENTAL

Active Ingredient/Active Moiety Ingredient Name Basis of Strength HYDROGEN PEROXIDE (UNII: BBX060AN9V) (HYDROGEN PEROXIDE - UNII: BBX060AN9V) HYDROGEN PEROXIDE UNII: BBX060AN9V) HYDROGEN PEROXIDE in 1 g

Inactive Ingredients				
Ingredient Name	Strength			
SORBITOL (UNII: 506T60A25R)				
MENTHOL (UNII: L7T10EIP3A)				
METHYL SALICYLATE (UNII: LAV5U5022Y)				
PHOSPHORIC ACID (UNII: E4GA8884NN)				
POTASSIUM SORBATE (UNII: 1VPU26JZZ4)				
WATER (UNII: 059QF0KO0R)				
POLYSORBATE 20 (UNII: 7T1F30V5YH)				
SACCHARIN SODIUM (UNII: SB8ZUX40TY)				
POLOXAMER 407 (UNII: TUF2IVW3M2)				
ALCOHOL (UNII: 3K9958V90M)				

Product Characteristics					
Color		Score			
Shape		Size			
Flavor	MINT (Clean Mint)	Imprint Code			
Contains					

P	Packaging					
#	Item Code	Package Description	Marketing Start Date	Marketing End Date		
1	NDC:59883-018- 87	1 in 1 BOX	07/15/2019			
1		85 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 Drug	M022	07/15/2019			

Labeler - DEN-MAT HOLDINGS, LLC. (809857704)

Revised: 11/2023 DEN-MAT HOLDINGS, LLC.