

PERIO ARMOR- 1.7% hydrogen peroxide gel
Gingi-Pak a Division of the Belport

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.

Perio Armor

Active Ingredient

Hydrogen Peroxide 1.7% (w/w)

Purpose

Wound Cleanser

Indication and Uses

For temporary use in cleansing minor oral wounds and treatment of inflammation resulting from dental procedures or other irritations of the mouth and gums. Perio Armor may be used for decreasing the presence of plaque, a known factor in the development of gingivitis and tooth decay.

Directions

For children under 2 years of age, consult a dentist or physician before use. For adults and children 2 years of age or older: 1. Remove cap and cut the tip of the tube at the narrow end. 2. Apply several drops of the gel directly onto the affected area in the mouth. 3. Leave the gel on the affected area for at least 60 seconds, then spit. 4. Use up to 4 times daily after meals, at bedtime, or as directed by a dentist or physician.

Other Information

Store at room temperature between 20-25° C (68-77° F) and away from direct sunlight. Do not use if the tube has been damaged or tampered in any way

Inactive Ingredients (mint flavor)

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

Question or comments?

(800)437-1514 or www.gingi-pak.com.

Warning

Do not use

Do not use Perio Armor for more than 7 days unless directed by your dentist or physician.

Stop use

Stop use and consult your dentist or physician if: • Symptoms do not improve within 7 days • Irritation, pain, or redness persists or worsens • Swelling, rash, or fever develops

Keep out of reach of children.

Inactive Ingredients (Strawberry and Bubblegum)

Ethyl Alcohol, Phosphoric Acide, Poloxamer 407, Polysorbate 20, Potassium Sorbate, Sodium Saccharin, Sorbitol, Water, Natural and Artificial Flavors

Principle Display



Principle Display

Since 1955
GINGI-PAK[®]

NDC# 10129-020-03

Perio Armor



Cotton Candy

Oral Cleansing Gel
1.7% Hydrogen Peroxide

NET WT 3.0 OZ (86 g)

AI
PI

Principle Display

Since 1955
GINGI-PAK[®]

NDC# 10129-018-03

Perio Armor



Mint Flavor

Oral Cleansing Gel
1.7% Hydrogen Peroxide

NET WT 3.0 OZ (86 g)

AI
PI

Principal Display

Since 1955
GINGI-PAK[®]

NDC# 10129-032-03

Perio Armor



Bubblegum

Oral Cleansing Gel
1.7% Hydrogen Peroxide

NET WT 3.0 OZ (85 g)

PERIO ARMOR

1.7% hydrogen peroxide gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:10129-018
Route of Administration	DENTAL, PERIODONTAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
HYDROGEN PEROXIDE (UNII: BBX060AN9V) (HYDROGEN PEROXIDE - UNII:BBX060AN9V)	HYDROGEN PEROXIDE	17 g in 100 mL

Inactive Ingredients

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

Product Characteristics

Color		Score	
Shape		Size	
Flavor	MINT	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:10129-018-03	1 in 1 BOX	08/15/2022	
1		88.7 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 not final	part356	08/15/2022	

PERIO ARMOR

1.7% hydrogen peroxide gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:10129-019
Route of Administration	DENTAL, PERIODONTAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
HYDROGEN PEROXIDE (UNII: BBX060AN9V) (HYDROGEN PEROXIDE - UNII:BBX060AN9V)	HYDROGEN PEROXIDE	17 g in 100 mL

Inactive Ingredients

Ingredient Name	Strength
ALCOHOL (UNII: 3K9958V90M)	
PHOSPHORIC ACID (UNII: E4GA8884NN)	
SORBITOL (UNII: 506T60A25R)	
WATER (UNII: 059QF0KO0R)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
POLYSORBATE 20 (UNII: 7T1F30V5YH)	
POLOXAMER 407 (UNII: TUF2IWW3M2)	
POTASSIUM SORBATE (UNII: 1VPU26JZZ4)	

Product Characteristics

Color		Score	
Shape		Size	
Flavor	STRAWBERRY	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:10129-019-03	1 in 1 BOX	08/15/2022	
1		88.7 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 not final	part356	08/15/2022	

PERIO ARMOR

1.7% hydrogen peroxide gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:10129-020
Route of Administration	DENTAL, PERIODONTAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
HYDROGEN PEROXIDE (UNII: BBX060AN9V) (HYDROGEN PEROXIDE - UNII:BBX060AN9V)	HYDROGEN PEROXIDE	17 g in 100 mL

Inactive Ingredients

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

Product Characteristics

Color		Score	
Shape		Size	
Flavor	COTTON CANDY	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:10129-020-03	1 in 1 BOX	08/15/2022	10/25/2022
1		88.7 mL in 1 TUBE; Type 0: Not a Combination Product		

Marketing Information

Marketing	Application Number or Monograph	Marketing Start	Marketing End
-----------	---------------------------------	-----------------	---------------

Category	Citation	Date	Date
OTC monograph not final	part356	08/15/2022	10/25/2022

PERIO ARMOR

1.7% hydrogen peroxide gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:10129-032
Route of Administration	DENTAL, PERIODONTAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
HYDROGEN PEROXIDE (UNII: BBX060AN9V) (HYDROGEN PEROXIDE - UNII:BBX060AN9V)	HYDROGEN PEROXIDE	17 g in 100 mL

Inactive Ingredients

Ingredient Name	Strength
ALCOHOL (UNII: 3K9958V90M)	
PHOSPHORIC ACID (UNII: E4GA8884NN)	
SORBITOL (UNII: 506T60A25R)	
WATER (UNII: 059QF0KO0R)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
POLYSORBATE 20 (UNII: 7T1F30V5YH)	
POLOXAMER 407 (UNII: TUF21VW3M2)	
POTASSIUM SORBATE (UNII: 1VPU26JZZ4)	

Product Characteristics

Color		Score	
Shape		Size	
Flavor	BUBBLE GUM	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:10129-032-03	1 in 1 BOX	10/25/2022	
1		88.7 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 not final	part356	10/25/2022	

Labeler - Gingi-Pak a Division of the Belport (008480121)

Registrant - Jeff Nichols (008480121)

Establishment

Name	Address	ID/FEI	Business Operations
Gingi-Pak a Division of the Belport		008480121	manufacture(10129-018, 10129-019, 10129-020, 10129-032)

Revised: 10/2022

Gingi-Pak a Division of the Belport