

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

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-X

Active Ingredients

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

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

Question or Comments?

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

Warnings

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

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.

Since 1955
GINGI-PAK®

NDC# 10129-039-03

Perio Armor X



Strawberry

Oral Cleansing Gel

1.7% Hydrogen Peroxide with Xylitol

NET WT 3.0 OZ (86 g)

AI Pi

Since 1955
GINGI-PAK®

NDC# 10129-042-03

Perio Armor X



Cotton Candy

Oral Cleansing Gel

1.7% Hydrogen Peroxide with Xylitol

NET WT 3.0 OZ (86 g)

AI Pi

Since 1955
GINGI-PAK®

NDC# 10129-038-03

Perio Armor X



Mint Flavor

Oral Cleansing Gel
1.7% Hydrogen Peroxide with Xylitol

NET WT 3.0 OZ (86 g)

PERIO ARMOR-X

1.7% hydrogen peroxide gel

Product Information

| | | | |
|--------------------------------|---------------------|---------------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:10129-039 |
| Route of Administration | PERIODONTAL, DENTAL | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---|-------------------|----------------|
| HYDROGEN PEROXIDE (UNII: BBX060AN9V) (HYDROGEN PEROXIDE - UNII:BBX060AN9V) | HYDROGEN PEROXIDE | 1.7 g in 100 g |

Inactive Ingredients

| Ingredient Name | Strength |
|---|----------|
| MENTHOL (UNII: L7T10EIP3A) | |
| POTASSIUM SORBATE (UNII: 1VPU26JZZ4) | |
| POLYSORBATE 20 (UNII: 7T1F30V5YH) | |
| POLOXAMER 407 (UNII: TUF2IVW3M2) | |
| WATER (UNII: 059QF0KO0R) | |
| ALCOHOL (UNII: 3K9958V90M) | |
| XYLITOL (UNII: VCQ006KQ1E) | |
| PHOSPHORIC ACID (UNII: E4GA8884NN) | |
| SORBITOL (UNII: 506T60A25R) | |
| METHYL SALICYLATE (UNII: LAV5U5022Y) | |

Product Characteristics

| | | | |
|---------------|------------|---------------------|--|
| Color | | Score | |
| Shape | | Size | |
| Flavor | STRAWBERRY | Imprint Code | |

| | |
|-----------------|--|
| Contains | |
|-----------------|--|

| | | | | |
|------------------|--|--|--|--|
| Packaging | | | | |
|------------------|--|--|--|--|

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|---|----------------------|--------------------|
| 1 | NDC:10129-039-03 | 1 in 1 BOX | 08/15/2022 | |
| 1 | | 86 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 | 08/15/2022 | |

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| PERIO ARMOR-X |
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1.7% hydrogen peroxide gel

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|----------------------------|--|--|--|
| Product Information | | | |
|----------------------------|--|--|--|

| | | | |
|--------------------------------|---------------------|---------------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:10129-038 |
| Route of Administration | PERIODONTAL, DENTAL | | |

| | | |
|--|--|--|
| Active Ingredient/Active Moiety | | |
|--|--|--|

| Ingredient Name | Basis of Strength | Strength |
|---|-------------------|----------------|
| HYDROGEN PEROXIDE (UNII: BBX060AN9V) (HYDROGEN PEROXIDE - UNII:BBX060AN9V) | HYDROGEN PEROXIDE | 1.7 g in 100 g |

| | |
|-----------------------------|--|
| Inactive Ingredients | |
|-----------------------------|--|

| Ingredient Name | Strength |
|---|----------|
| MENTHOL (UNII: L7T10EIP3A) | |
| POTASSIUM SORBATE (UNII: 1VPU26JZZ4) | |
| POLYSORBATE 20 (UNII: 7T1F30V5YH) | |
| POLOXAMER 407 (UNII: TUF21VW3M2) | |
| WATER (UNII: 059QF0KO0R) | |
| METHYL SALICYLATE (UNII: LAV5U5022Y) | |
| ALCOHOL (UNII: 3K9958V90M) | |
| XYLITOL (UNII: VCQ006KQ1E) | |
| PHOSPHORIC ACID (UNII: E4GA8884NN) | |
| SORBITOL (UNII: 506T60A25R) | |

| Product Characteristics | | | | |
|-------------------------|--|---|----------------------|--------------------|
| Color | | Score | | |
| Shape | | Size | | |
| Flavor | MINT | Imprint Code | | |
| Contains | | | | |
| Packaging | | | | |
| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
| 1 | NDC:10129-038-03 | 1 in 1 BOX | 08/15/2022 | |
| 1 | | 86 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 | 08/15/2022 | | |

| PERIO ARMOR-X | | | |
|--|---------------------|--------------------|---------------|
| 1.7% hydrogen peroxide gel | | | |
| Product Information | | | |
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:10129-042 |
| Route of Administration | PERIODONTAL, DENTAL | | |
| Active Ingredient/Active Moiety | | | |
| Ingredient Name | Basis of Strength | Strength | |
| HYDROGEN PEROXIDE (UNII: BBX060AN9V) (HYDROGEN PEROXIDE - UNII:BBX060AN9V) | HYDROGEN PEROXIDE | 1.7 g in 100 g | |
| Inactive Ingredients | | | |
| Ingredient Name | Strength | | |
| MENTHOL (UNII: L7T10EIP3A) | | | |
| POTASSIUM SORBATE (UNII: 1VPU26JZ4) | | | |
| POLYSORBATE 20 (UNII: 7T1F30V5YH) | | | |
| POLOXAMER 407 (UNII: TUF2IVW3M2) | | | |
| WATER (UNII: 059QF0KO0R) | | | |
| ALCOHOL (UNII: 3K9958V90M) | | | |
| XYLITOL (UNII: VCQ006KQ1E) | | | |
| PHOSPHORIC ACID (UNII: E4GA8884NN) | | | |

| | |
|---|--|
| SORBITOL (UNII: 506T60A25R) | |
| METHYL SALICYLATE (UNII: LAV5U5022Y) | |

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:10129-042-03 | 1 in 1 BOX | 08/15/2022 | |
| 1 | | 86 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 | 08/15/2022 | |

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(10129-038, 10129-039, 10129-042) |

Revised: 8/2022

Gingi-Pak a Division of the Belport