

PERIO DAILY DEFENSE- hydrogen peroxide gel
Den-Mat Holdings, 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.

Active ingredient

Hydrogen Peroxide 1.7% w/w

Purpose

Wound Cleaner

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 Daily Defense may be used for lessening the presence of plaque, a known factor in development of gingivitis.

Warnings

Do not use Perio Daily Defense 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 section

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

Directions

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

For adults and children 2 years of age or 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 at bedtime, or as directed by a dentist or physician.

Other Information

Store at controlled room temperature, 20-25° 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.

Labeling

<p>Perio Daily Defense™</p>  <p>Oral Cleansing Gel 1.7% Hydrogen Peroxide</p>  CLEAN MINT <p>Net Wt. 3 oz. (85 g)</p>	<p>Drug Facts</p> <table border="1"><thead><tr><th>Active Ingredients</th><th>Purpose</th></tr></thead><tbody><tr><td>Hydrogen Peroxide 1.7% w/w.....</td><td>Wound Cleaner</td></tr></tbody></table> <p>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 Daily Defense may be used for lessening the presence of plaque, a known factor in development of gingivitis.</p> <p>Warnings Do not use Perio Daily Defense Gel for more than 7 days unless directed by your dentist or physician. Stop use and ask your dentist or physician if:</p> <ul style="list-style-type: none">• Symptoms of wounds or inflammation do not improve within 7 days• Irritation, pain or redness persists or worsens• Swelling, rash or fever develops <p>Keep out of reach of children. Children under 12 years of age should be supervised when using this product.</p> <p>Directions For children under 2 years of age, consult a dentist or physician. For adults and children 2 years of age or older:</p> <ol style="list-style-type: none">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 at bedtime, or as directed by a dentist or physician. <p>Other Information Store at controlled room temperature, 20-25° C (68-77° F) and away from direct sunlight. For your protection, do not use if tamper seal on box is broken or missing.</p> <p>Inactive Ingredients Ethyl Alcohol, Menthol, Methyl Salicylate, Phosphoric Acid, Poloxamer 407, Polysorbate 20, Potassium Sorbate, Sodium Saccharin, Sorbitol, Water.</p>	Active Ingredients	Purpose	Hydrogen Peroxide 1.7% w/w.....	Wound Cleaner	<p>Perio Daily Defense™</p>  <p>Oral Cleansing Gel 1.7% Hydrogen Peroxide</p>  CLEAN MINT <p>Net Wt. 3 oz. (85 g)</p>	<p>Manufactured for Den-Mat Holdings, LLC 1017 W. Central Avenue Lompoc, CA 93436</p> <p>Questions or comments? Email: consumer@denmat.com</p> <p>©2018 Den-Mat Holdings, LLC All rights reserved. 090332600 R:0 11/18SN</p>
Active Ingredients	Purpose						
Hydrogen Peroxide 1.7% w/w.....	Wound Cleaner						

PERIO DAILY DEFENSE

hydrogen peroxide gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:59883-017
Route of Administration	TOPICAL		

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

Product Characteristics

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

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:59883-017-03	1 g in 1 TUBE; Type 0: Not a Combination Product	08/31/2022	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not		08/31/2022	

final	part 550	08/31/2022	
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Labeler - Den-Mat Holdings, LLC (809857704)

Establishment

Name	Address	ID/FEI	Business Operations
Dental Technologies, Inc.		148312838	manufacture(59883-017) , label(59883-017) , pack(59883-017)

Revised: 8/2022

Den-Mat Holdings, LLC