

**REDDYPORT ANTISEPTIC ORAL RINSE- hydrogen peroxide mouthwash**  
**REDDYPORT ANTIPLAQUE SOLUTION- cetylpyridinium chloride rinse**  
**REDDYPORT NIV MAINTENANCE KIT- cetylpyridinium chloride and hydrogen peroxide**  
**SMD Manufacturing**

*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.*

**CONTENTS OF PACKAGE**

- 1 PREP PACK
  - Yankauer
  - Hands
  - Connector
- 4 SUCTION SWAB PACKS
  - Suction swab
  - Applicator swab
  - Antiseptic oral rinse
  - Mouth moisturizer
- 2 SUCTION TOOTHBRUSH PACKS
  - Suction toothbrush
  - Applicator swab
  - Anti-plaque solution
  - Mouth moisturizer

**OPENING INSTRUCTIONS**

Open the ReddyPort 24 hour oral care kit by tearing off front cover. Remove and open the ReddyPort Prep Pack.

- Connect the suction handles to suction tubing. The suction tubing should be attached to a suction canister. If needed, use the included Y connector to split the suction tubing to allow both oral care and closed suctioning.
- Attach Yankauer to handle (Figure 1) and keep at bedside.

**YANKAUER**

- Insert the protective sheath into the suction tubing, ensuring the sheath is fully inserted.
- Insert the suction tube through the mouth, avoiding the oral cavity.
- To remove the yankauer, gently pull the protective sheath and suction tube away from the patient's mouth. Do not pull the suction tube out of the elbow (Figure 4).
- Remove the yankauer from the suction tubing and discard in a biohazard container.

**SUCTION SWAB & TOOTHBRUSH**

The suction swab and toothbrush are used to apply the oral care, clean, and moisturize fluid.

- Moisten the sponge or brush by rotating the protective guard and placing the sponge or brush in the appropriate fluid in the appropriate well (Figure 5).
- Insert the moistened sponge or toothbrush into the suction guard to cover it (Figure 6).
- With the sponge or toothbrush covering the suction guard, gently pull on the suction tubing using the finger grip (Figure 7).
- Gently advance the sponge or toothbrush into the mouth and perform oral care using the ReddyPort Elbow (Figure 8). Suction assess fluid by placing a finger over the suction port.
- Remove the sponge or toothbrush by gently pulling on the stick to release the sponge or toothbrush into the suction tubing and set aside or reuse according to the directions. Rinse the stick and suction tubing with water or mouth moisturizer.
- Remove the applicator swab (Figure 9).

**APPLICATOR SWAB**

The applicator swab is included in the suction swab pack and the suction toothbrush pack. It is used to moisten the mouth with water or mouth moisturizer.

- Apply water or mouth moisturizer to the sponge.
- Following the suction swab procedure, the applicator swab (Figure 8), and moisten the mouth with water or mouth moisturizer.
- Apply water or mouth moisturizer to the sponge and box as needed.
- Remove the applicator swab (Figure 9).

**WARNING: If a device using the finger grip on the prep pack is used, it is not recommended.**

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**PRODUCT INFORMATION**

- This NIV maintenance kit is designed for non-invasive ventilation patients.
- Use the ReddyPort Elbow using the ReddyPort Elbow.
- Store at room temperature.
- Do not use for nebulization.
- For information only.
- Non-sterile.

**Drug Facts: Anti-plaque Solution**

**Active ingredient:** Cetylpyridinium Chloride (CPC) 0.05% (0.1g Agent)

**Other ingredients:** Dextrose, Polysorbate 80, Sodium Chloride, Potassium Sorbate, Sorbic Acid, Sodium Benzoate, Sodium Saccharin, Sulfur Dioxide, USP Water for Injection.

**How to use:** See the instructions for use.

**Warnings:** Do not use if you are allergic to any of the ingredients. Do not use if you are allergic to any of the ingredients. Do not use if you are allergic to any of the ingredients.

**Directions:** See the instructions for use.

**Other information:** See the instructions for use.

**Questions or comments?** 800.899.0000

**Drug Facts: Antiseptic Oral Rinse**

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**REDDYPORT**

**24-HOUR NIV MAINTENANCE KIT**

For use with the ReddyPort Elbow (not included)

TEAR HERE

**Q4**

**REDDYPORT**

patient's name: \_\_\_\_\_

date: \_\_\_\_\_ time: \_\_\_\_\_

www.reddyport.com

8881704-1

Packaged in USA for:  
 SMD Manufacturing, LLC  
 Salt Lake City, Utah 84101  
 (801) 949-3336

Distributed in USA by ReddyPort Inc.  
 318 South 200 West, Suite 8A  
 Salt Lake City, Utah 84103

pat. www.reddyport.com  
 Product of USA and China  
 NDC # 73272-105-14  
 DC 009-6, Rev. 1

## Drug Facts: Antiseptic Oral Rinse

### Active Ingredients

Hydrogen Peroxide 1.5%.....Oral Agent

### Inactive Ingredients

Deionized Water, Glycerin, Spearmint Flavor, Sodium Saccharin, D&C Green #5

### Uses

- Helps remove plaque that leads to gingivitis
- Aids in the removal of phlegm, mucus, or other secretions in the temporary relief of discomfort due to sore throat and sore mouth

### Warnings: Stop use and ask a doctor if

- Swelling, rash, or fever develops
- Severe or persistent sore throat and sore throat with a high fever, headache, nausea, vomiting occurs
- Do not use more than 2 days or administer to children under 3 years of age unless directed by a physician
- Gingivities, bleeding, or redness persists for more than 2 weeks
- You have painful or swollen gums, pus from the gum line, loose teeth, or increasing spacing between the teeth. These may be a sign of symptoms or periodontitis, a serious form of gum disease

### Directions

- Adults and children 12 years of age and older, use as directed by dentist
- Children 6 years to 12 years of age, supervise use
- Children under 6 years of age, do not use
- Use only under health care practitioner's supervision
- Use no more than 4 times daily

### Other information

- This rinse is not intended to replace brushing or flossing
- Store at room temperature, avoid excessive heat and Freezing

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## REDDYPORT ANTISEPTIC ORAL RINSE

hydrogen peroxide mouthwash

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:73573-015
<b>Route of Administration</b>	BUCCAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>HYDROGEN PEROXIDE</b> (UNII: BBX060AN9V) (HYDROGEN PEROXIDE - UNII:BBX060AN9V)	HYDROGEN PEROXIDE	15 mg in 1 mL

### Inactive Ingredients

Ingredient Name	Strength
<b>D&amp;C GREEN NO. 5</b> (UNII: 8J6RDU8L9X)	

<b>SACCHARIN SODIUM</b> (UNII: SB8ZUX40TY)	
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	
<b>SPEARMINT</b> (UNII: J7I2T6IV1N)	

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:73573-015-15	14.8 mL in 1 CUP; Type 0: Not a Combination Product	01/22/2020	

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part356	01/22/2020	

## REDDYPORT ANTIPLAQUE SOLUTION

cetylpyridinium chloride rinse

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:73573-005
<b>Route of Administration</b>	ORAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>CETYLPIRIDINIUM CHLORIDE</b> (UNII: D9OM4SK49P) (CETYLPIRIDINIUM - UNII:CUB7JI0JV3)	CETYLPIRIDINIUM CHLORIDE	0.5 mg in 1 mL

### Inactive Ingredients

Ingredient Name	Strength
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>BENZOIC ACID</b> (UNII: 8SKN0B0MIM)	
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	
<b>SODIUM BENZOATE</b> (UNII: OJ245FE5EU)	
<b>SACCHARIN SODIUM</b> (UNII: SB8ZUX40TY)	
<b>D&amp;C GREEN NO. 5</b> (UNII: 8J6RDU8L9X)	
<b>D&amp;C RED NO. 33</b> (UNII: 9DBA0SBB0L)	
<b>SORBITOL</b> (UNII: 506T60A25R)	
<b>SPEARMINT</b> (UNII: J7I2T6IV1N)	



## Packaging

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OTC monograph not final	part356	01/22/2020	

## REDDYPORT NIV MAINTENANCE KIT

cetylpyridinium chloride and hydrogen peroxide kit

### Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:73573-155
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## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:73573-155-14	1 in 1 KIT; Type 1: Convenience Kit of Co-Package	01/14/2021	

## Quantity of Parts

Part #	Package Quantity	Total Product Quantity
Part 1	0 CUP, UNIT-DOSE	4 mL in 14.8
Part 2	0 CUP, UNIT-DOSE	2 mL in 14.8

## Part 1 of 2

## REDDYPORT ANTISEPTIC ORAL RINSE

hydrogen peroxide mouthwash

### Product Information

Item Code (Source)	NDC:73573-015
Route of Administration	BUCCAL

## Active Ingredient/Active Moiety

Active Ingredient/Active Moiety	Strength	Form	Route of Administration
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Ingredient Name		Basis of Strength	Strength	
HYDROGEN PEROXIDE (UNII: BBX060AN9V) (HYDROGEN PEROXIDE - UNII:BBX060AN9V)		HYDROGEN PEROXIDE	15 mg in 1 mL	
<b>Inactive Ingredients</b>				
Ingredient Name		Strength		
SPEARMINT (UNII: J7I2T6IV1N)				
SACCHARIN SODIUM (UNII: SB8ZUX40TY)				
D&C GREEN NO. 5 (UNII: 8J6RDU8L9X)				
WATER (UNII: 059QF0KO0R)				
GLYCERIN (UNII: PDC6A3C0OX)				
<b>Packaging</b>				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		14 mL in 1 CUP, UNIT-DOSE; Type 1: Convenience Kit of Co-Package		
<b>Marketing Information</b>				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph not final	part356	01/22/2021		
<b>Part 2 of 2</b>				
<b>REDDYPORT ANTIPLAQUE SOLUTION</b>				
cetylpyridinium chloride rinse				
<b>Product Information</b>				
Item Code (Source)	NDC:73573-005			
Route of Administration	ORAL			
<b>Active Ingredient/Active Moiety</b>				
Ingredient Name		Basis of Strength	Strength	
CETYLPYRIDINIUM CHLORIDE (UNII: D9OM4SK49P) (CETYLPYRIDINIUM - UNII:CUB7J10JV3)		CETYLPYRIDINIUM CHLORIDE	0.5 mg in 1 mL	
<b>Inactive Ingredients</b>				
Ingredient Name		Strength		

<b>D&amp;C RED NO. 33</b> (UNII: 9DBA05BB0L)	
<b>SPEARMINT</b> (UNII: J7I2T6IV1N)	
<b>BENZOIC ACID</b> (UNII: 8SKN0B0MIM)	
<b>SACCHARIN SODIUM</b> (UNII: SB8ZUX40TY)	
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	
<b>SORBITOL</b> (UNII: 506T60A25R)	
<b>D&amp;C GREEN NO. 5</b> (UNII: 8J6RDU8L9X)	
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>SODIUM BENZOATE</b> (UNII: OJ245FE5EU)	

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		14 mL in 1 CUP, UNIT-DOSE; Type 1: Convenience Kit of Co-Package		

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part356	01/22/2021	

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part356	01/14/2021	

**Labeler** - SMD Manufacturing (070849038)

### Establishment

Name	Address	ID/FEI	Business Operations
Elba, Inc.		108428483	manufacture(73573-005, 73573-015, 73573-155)

Revised: 1/2021

SMD Manufacturing