

ORAL CARE Q4 KIT- hydrogen peroxide

Halyard Health

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.

Halyard

24-Hour Oral Care Kit

Oral Debriding Agent

Drug Facts

Active Ingredient

Hydrogen Peroxide 1.5%

Purpose

Oral Debriding Agent

Uses

- Aids in the removal of phlegm, mucus, or other secretions in the temporary relief of discomfort due to occasional sore throat and sore mouth.

Warnings

Stop use and ask a doctor if:

- Swelling, rash, or fever develop.
- Severe or persistent sore throat or sore throat accompanied by high fever, headache, nausea, and vomiting occurs.
- Do not use more than 2 days or administer to children under 3 years of age unless directed by a physician.

Keep out of reach of children under 3 years of age.

Directions

- Topical dosage for adults and children 3 years of age and older is a rinse used no more than 4 times daily. For children under 3 years of age, there is no recommended dosage except under the advice and supervision of a dentist or doctor.
- Use only under health care practitioners supervision.

Other Information

- Store at room temperature.

Inactive Ingredients

Purified Water, Glycerin, Flavor, Sodium Saccharin

Questions or Comments?

1-800-KCHELPS

Antiplaque Solution

Drug Facts

Active Ingredient

Cetylpyridinium Chloride 0.05%

Purpose

Antigingivitis/Antiplaque

Uses

- Helps remove plaque that leads to gingivitis.

Warnings

Stop use and ask a doctor if:

- Gingivitis, 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 signs or symptoms of periodontitis, a serious form of gum disease.

Keep out of reach of children under 6 years of age.

If more than used for rinsing is accidentally swallowed, get medical help or contact a Poison Control Center right away.

Directions

- Adults and children 12 years of age and older: Use as directed by a dentist. DO not swallow the rinse.
- Children 6 years to under 12 years of age: supervised use.
- Children under 6 years of age: do not use.
- Use only under health care practitioner's supervision.

Other Information

- This rinse is not intended to replace brushing or flossing.
- Store at room temperature.

Inactive Ingredients

Purified Water, Glycerin, Sorbitol, Flavor, Benzoic Acid, Sodium Benzoate, Sodium Saccharin, D&C Green 5

Questions or Comments?

1-844-425-9273

Manufactured by Kimberly-Clark, Roswell, GA 30076 USA

Distributed in the U.S. by Kimberly-Clark Global Sales, LLC, Roswell, GA 30076 USA

PRINCIPAL DISPLAY PANEL - Kit Carton

HALYARD*

24-HOUR

ORAL CARE KIT

with BALLARD* Technology

q4

1

HALYARD*

Prep

Pack

2

HALYARD*

Toothbrush

Packs

4

HALYARD*

Suction Swab

Packs with H₂O₂

2

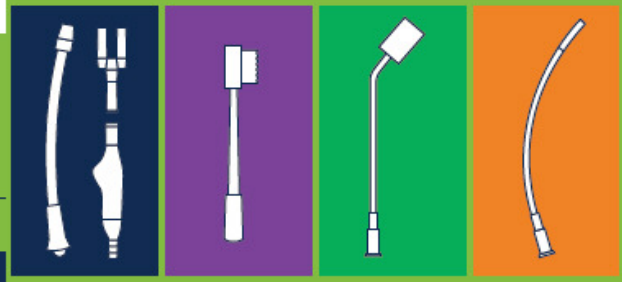
HALYARD*

Suction Catheter

Packs

24-HOUR ORAL CARE KIT

with BALLARD* Technology

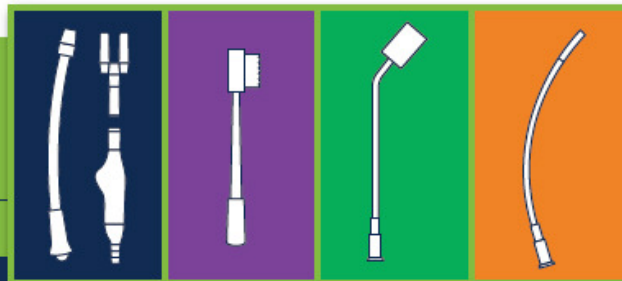


q4



24-HOUR ORAL CARE KIT

with BALLARD* Technology



q4

1 HALYARD*
Prep
Pack

2 HALYARD*
Toothbrush
Packs

4 HALYARD*
Suction Swab
Packs with H₂O₂

2 HALYARD*
Suction Catheter
Packs

Manufactured by Halyard Health, Inc.,
5405 Windward Parkway, Alpharetta, GA 30004 USA
Distributed in the USA by Halyard Sales, LLC, Alpharetta, GA 30004
In USA, please call 1-844-425-9273 • halyardhealth.com

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U.S. Patent No: 6,632,091

Product of Mexico and China

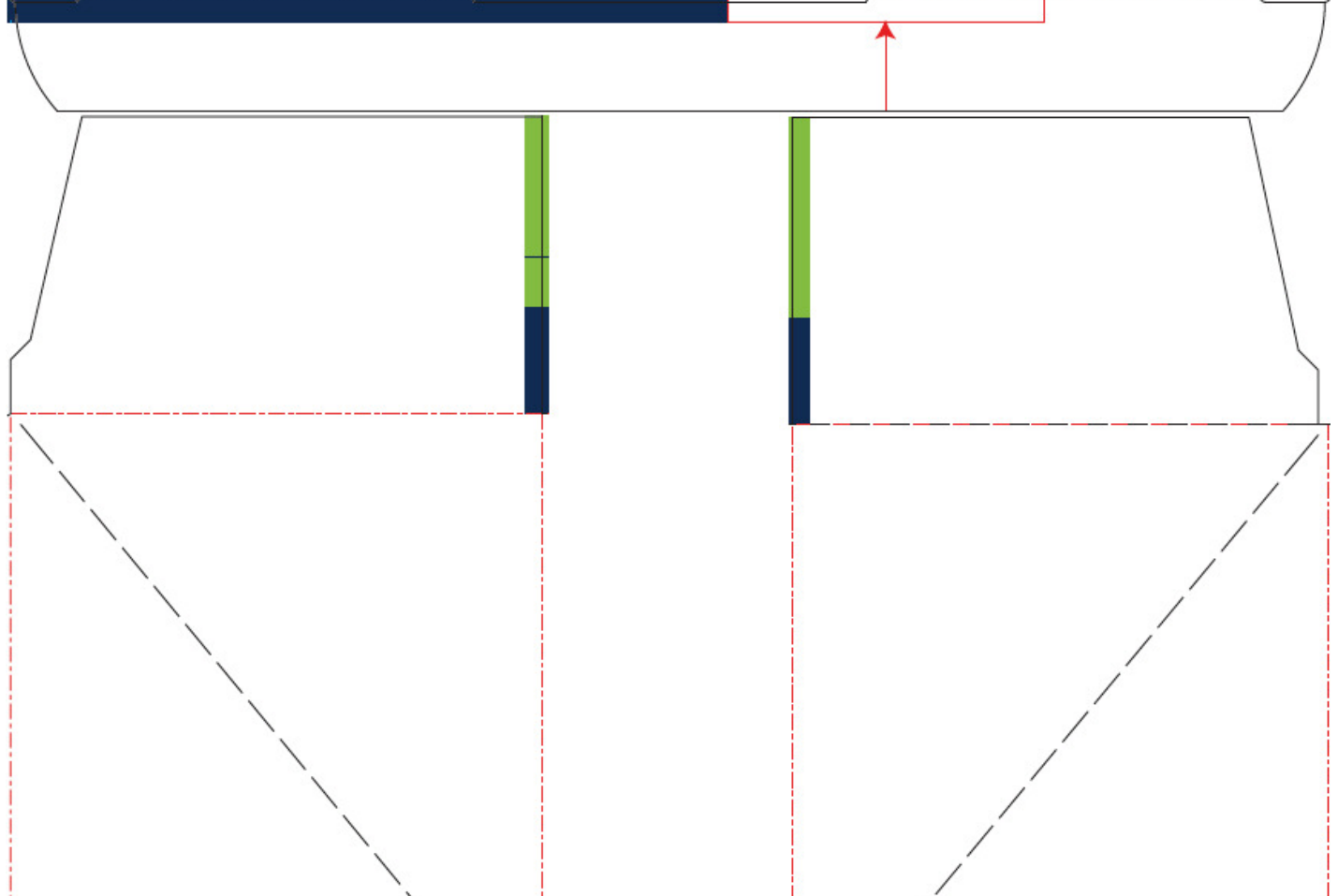
01-H1-060-0-00 / 70169556

REF 97021

NDC 69697-977-01

Expiration
Date

LOT



Mouth Moisturizer Ingredients

Deionized Water, Glycerin, Soybean Oil, Carboxymethylcellulose (CMC), Polysorbate 80, Sorbitol, Vitamin E / Tocopherol Acetate, Spearmint Flavor, Sodium Benzoate, Xylitol, Citric Acid, Sodium Chloride

Oral Debriding Agent

Drug Facts

Active Ingredient	Purpose
Hydrogen Peroxide 1.5%	Oral Debriding Agent

Uses

- Aids in the removal of phlegm, mucus, or other secretions in the temporary relief of discomfort due to occasional sore throat and sore mouth.

Warnings

Stop use and ask a doctor if:

- Swelling, rash, or fever develop.
- Severe or persistent sore throat or sore throat accompanied by high fever, headache, nausea, and vomiting occurs.
- Do not use more than 2 days or administer to children under 3 years of age unless directed by a physician.

Keep out of reach of children under 3 years of age.

Directions

- Topical dosage for adults and children 3 years of age and older is a rinse used no more than 4 times daily. For children under 3 years of age, there is no recommended dosage except under the advice and supervision of a dentist or doctor.
- Use only under health care practitioners supervision.

Other Information

- Store at room temperature.

Inactive Ingredients

Purified Water, Glycerin, Flavor, Sodium Saccharin

Questions or Comments?

1-844-425-9273

Antiplaque Solution

Drug Facts

Active Ingredient	Purpose
Cetylpyridinium Chloride 0.05%	Antigingivitis/Antiplaque

Uses

- Helps remove plaque that leads to gingivitis.

Warnings

Stop use and ask a doctor if:

- Gingivitis, 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 signs or symptoms of periodontitis, a serious form of gum disease.

Keep out of reach of children under 6 years of age.

If more than used for rinsing is accidentally swallowed, get medical help or contact a Poison Control Center right away.

Directions

- Adults and children 12 years of age and older: Use as directed by a dentist. Do not swallow the rinse.
- Children 6 years to under 12 years of age: supervised use.
- Children under 6 years of age: do not use.
- Use only under health care practitioner's supervision.

Other Information

- This rinse is not intended to replace brushing or flossing.
- Store at room temperature.

Inactive Ingredients

Purified Water, Glycerin, Sorbitol, Flavor, Benzoic Acid, Sodium Benzoate, Sodium Saccharin, D&C Green 5

Questions or Comments?

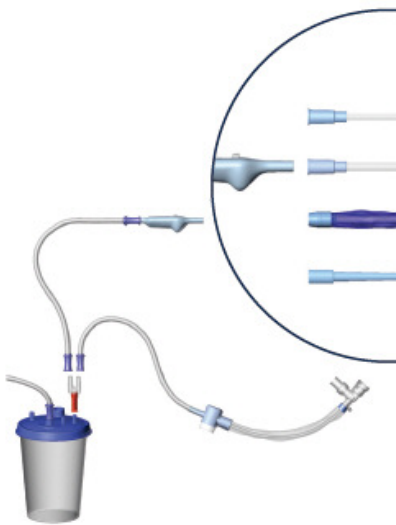
1-844-425-9273

Instructions for Use: Oral care should be performed per institutional protocol. ** For single patient use. Patients with altered levels of consciousness or who cannot comprehend commands may require use of a bite block. See instructions for use below.

Prep Pack Assembly



- Select HALYARD® Prep Pack from kit and open package.
- Connect stepped adapter of handle to suction tubing. Attach Y-connector to suction port. Then attach oral care suction tube to one Y-connector port and closed suction tube to the other. (Use the Y-connector only if using a single suction canister for both closed suctioning and oral care.)
- Attach Yankauer to handle.

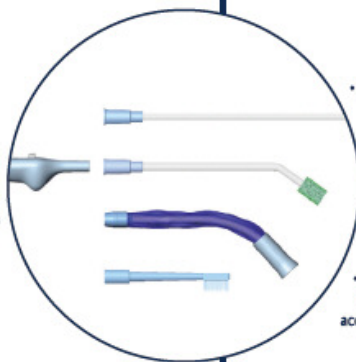


- To store, clip handle to top of suction tubing in upright position.

Yankauer Assembly and Use



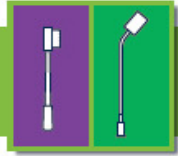
- Attach Yankauer to handle.
- Slide cleaning sleeve toward handle.
- To apply suction, slide switch to ON.
- Suction and clean oral cavity.
- After suctioning, advance cleaning sleeve toward tip to clean and dry the Yankauer.



- With suction still on, immerse Yankauer tip in sterile water or appropriate solution to clear Yankauer and suction tubing.
- Slide switch to OFF. (Switch should remain in OFF position when Yankauer is not in use.)
- To store, clip handle to top of suction tubing in upright position.
- Note: discard tubing, Y-adapter, handle, and Yankauer after using for 24 hours or according to protocol.



Toothbrush and Suction Swab Pack Assembly and Use



- Toothbrush or Suction Swab**
- Select HALYARD® Toothbrush or Suction Swab pack from kit and open package.
 - Remove Yankauer from handle and set aside. Attach tool.
 - Peel back solution dispenser lid and moisten tool.
 - To apply suction, slide switch to ON.
 - Clean and suction oral cavity using appropriate tool according to hospital protocol.
 - Slide switch to OFF.
 - Remove tool from handle and discard.
 - Reattach Yankauer to handle and clip to suction tubing.

- Applicator Swab and Mouth Moisturizer**
- Remove applicator swab and coat with moisturizer.
 - Apply moisturizer to lips and mouth.
 - Discard after use.

Suction Catheter Pack Assembly and Use



- Select HALYARD® Catheter Pack from kit and open package.
- Remove Yankauer from handle and set aside. Attach catheter.
- To apply suction, slide switch to ON.
- Suction and clean oropharyngeal cavity.
- Slide switch to OFF.
- Remove catheter from handle and discard.
- Reattach Yankauer to handle and clip to suction tubing.

**See graphics on the inner panel of the kit for a recommended order of use of components to support a typical q4h oral care protocol. The Suction Catheter Packs may be used as needed. For convenience, the start time may be entered in the blank arrow.

Nonsterile	Disposable	Not made with natural rubber latex	For use by a healthcare professional	Store at room temperature	REF 97021

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:69697-986
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Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69697-986-01	1 in 1 CARTON		

Quantity of Parts

Part #	Package Quantity	Total Product Quantity
Part 1	4 CUP, UNIT-DOSE	56 mL
Part 2	2 CUP, UNIT-DOSE	28 mL
Part 3	6 TUBE	60 g

Part 1 of 3

HYDROGEN PEROXIDE

hydrogen peroxide mouthwash

Product Information

Route of Administration	ORAL
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Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Hydrogen peroxide (UNII: BBX060AN9V) (Hydrogen peroxide - UNII:BBX060AN9V)	Hydrogen peroxide	0.015 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
Water (UNII: 059QF0KO0R)	
Glycerin (UNII: PDC6A3C0OX)	
Mint (UNII: FV98Z8G1TP)	
Saccharin Sodium Dihydrate (UNII: SB8ZUX40TY)	

Product Characteristics

Color		Score	
Shape		Size	
Flavor	MINT	Imprint Code	
Contains			

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	08/26/2008	

Part 2 of 3**CETYLPIRIDINIUM CHLORIDE**

cetylpyridinium chloride mouthwash

Product Information

Route of Administration	ORAL
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Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Cetylpyridinium Chloride (UNII: D9OM4SK49P) (Cetylpyridinium - UNII:CUB7JI0JV3)	Cetylpyridinium Chloride	0.0005 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
Water (UNII: 059QF0KO0R)	
Benzoic Acid (UNII: 8SKN0B0MIM)	
Saccharin Sodium Dihydrate (UNII: SB8ZUX40TY)	
Sodium Benzoate (UNII: OJ245FE5EU)	
Glycerin (UNII: PDC6A3C0OX)	
D&C Green No. 5 (UNII: 8J6RDU8L9X)	
Sorbitol (UNII: 506T60A25R)	
Mint (UNII: FV98Z8G1TP)	

Product Characteristics

Color	BLUE	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

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	03/13/2008	

Part 3 of 3

MOUTH MOISTURIZER

other oral hygiene products salve

Product Information

Route of Administration	ORAL
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Other Ingredients

Ingredient Kind	Ingredient Name	Quantity
INGR	Water (UNII: 059QF0KO0R)	
INGR	Xylitol (UNII: VCQ006KQ1E)	
INGR	Sodium Benzoate (UNII: OJ245FE5EU)	
INGR	Aloe Vera Flower (UNII: 575DY8C1ER)	
INGR	Propylene Glycol (UNII: 6DC9Q167V3)	
INGR	Potassium Sorbate (UNII: 1VPU26JZZ4)	
INGR	Sorbitol (UNII: 506T60A25R)	
INGR	Hydroxypropyl Cellulose (Type H) (UNII: RFW2ET671P)	
INGR	Dimethicone (UNII: 92RU3N3Y1O)	
INGR	Potassium Chloride (UNII: 660YQ98I10)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		10 g in 1 TUBE; Type 1: Convenience Kit of Co-Package		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
Cosmetic		06/25/2008	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part356	03/13/2008	

Labeler - Halyard Health (079617666)

Establishment

Name	Address	ID/FEI	Business Operations
Avent		049316284	MANUFACTURE(69697-986)

Establishment

Name	Address	ID/FEI	Business Operations
Elba		108428483	MANUFACTURE(69697-986)

Establishment

Name	Address	ID/FEI	Business Operations
Hi Tech Pharmacal		101196749	MANUFACTURE(69697-986)

Revised: 1/2016

Halyard Health