Q2 ORAL CARE KIT WITH CHG- hydrogen peroxide and chlorhexidine gluconate
Halyard Health

Halyard
24-Hour Oral Care Kit Q2

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?

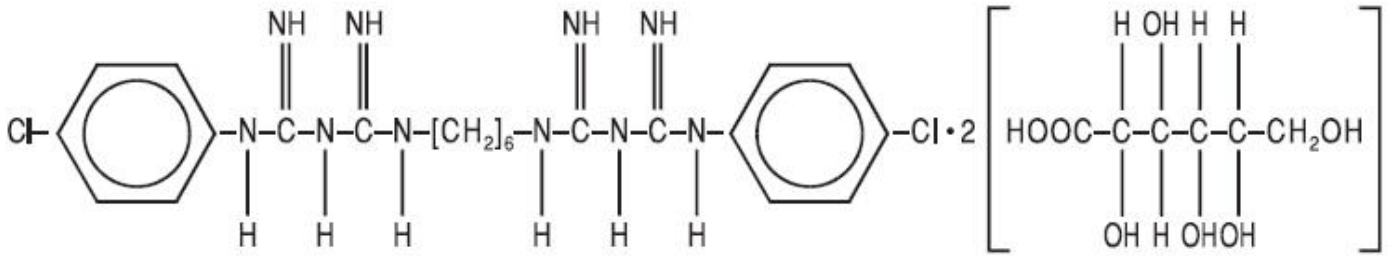
1-844-425-9273

CHLORHEXIDINE GLUCONATE ORAL RINSE, 0.12%

Rx Only

DESCRIPTION

Chlorhexidine Gluconate Oral Rinse, 0.12% is an oral rinse containing 0.12% chlorhexidine gluconate (1, 1'-hexamethylene bis[5-(p-chlorophenyl) biguanide] di-D-gluconate) in a base containing 11.6% v/v alcohol, FD&C Blue No. 1, glycerin, PEG-40 sorbitan diisostearate, peppermint flavor, sodium saccharin, and purified water. Chlorhexidine Gluconate Oral Rinse is a near-neutral solution (pH range 5-7). Chlorhexidine gluconate is a salt of chlorhexidine and gluconic acid. Its structural formula is: $C_{22}H_{30}Cl_2N_{10}•2C_6H_{12}O_7$ MW = 897.8



CLINICAL PHARMACOLOGY

Chlorhexidine Gluconate Oral Rinse, 0.12% provides antimicrobial activity during oral rinsing. The clinical significance of 0.12% chlorhexidine gluconate oral rinse's anti-microbial activities is not clear. Microbiological sampling of plaque has shown a general reduction of counts of certain assayed bacteria, both aerobic and anaerobic, ranging from 54-97% through six months use. Use of chlorhexidine gluconate oral rinse in a six month clinical study did not result in any significant changes in bacterial resistance, overgrowth of potentially opportunistic organisms or other adverse changes in the oral microbial ecosystem. Three months after chlorhexidine gluconate use was discontinued, the number of bacteria in plaque had returned to baseline levels and resistance of plaque bacteria to chlorhexidine gluconate was equal to that at baseline.

PHARMACOKINETICS

Pharmacokinetic studies with a 0.12% chlorhexidine gluconate oral rinse indicate approximately 30% of the active ingredient, chlorhexidine gluconate, is retained in the oral cavity following rinsing. This retained drug is slowly released into the oral fluids. Studies conducted on human subjects and animals demonstrate chlorhexidine gluconate is poorly absorbed from the gastrointestinal tract. The mean plasma level of chlorhexidine gluconate reached a peak of 0.206 µg/g in humans 30 minutes after they ingested a 300-mg dose of the drug. Detectable levels of chlorhexidine gluconate were not present in the plasma of these subjects 12 hours after the compound was administered. Excretion of chlorhexidine gluconate occurred primarily through the feces (~90%). Less than 1% of the chlorhexidine gluconate ingested by these subjects was excreted in the urine.

INDICATIONS AND USAGE

16 oz. Chlorhexidine Gluconate Oral Rinse, 0.12% - Chlorhexidine Gluconate Oral Rinse, 0.12% is indicated for use between dental visits as part of a professional program for the treatment of gingivitis as characterized by redness and swelling of the gingivae, including gingival bleeding upon probing. Chlorhexidine Gluconate Oral Rinse, 0.12% has not been tested among patients with acute necrotizing

ulcerative gingivitis (ANUG). For patients having coexisting gingivitis and periodontitis, see **PRECAUTIONS**.

CONTRAINDICATIONS

Chlorhexidine Gluconate Oral Rinse, 0.12% should not be used by persons who are known to be hypersensitive to chlorhexidine gluconate or other formula ingredients.

WARNINGS

The effect of Chlorhexidine Gluconate Oral Rinse, 0.12% on periodontitis has not been determined. An increase in supragingival calculus was noted in clinical testing in users of chlorhexidine gluconate oral rinse compared with control users. It is not known if chlorhexicine gluconate use results in an increase in subgingival calculus. Calculus deposits should be removed by a dental prophylaxis at intervals not greater than six months. Hypersensitivity and generalized allergic reactions have occurred. See **CONTRAINDICATIONS**.

PRECAUTIONS

General

1. For patients having coexisting gingivitis and periodontitis, the presence or absence of gingival inflammation following treatment with Chlorhexidine Gluconate Oral Rinse, 0.12% should not be used as a major indicator of underlying periodontitis.
2. Chlorhexidine Gluconate Oral Rinse, 0.12% can cause staining of oral surfaces, such as tooth surfaces, restorations, and the dorsum of the tongue. Not all patients will experience a visually significant increase in toothstaining. In clinical testing, 56% of chlorhexidine gluconate oral rinse users exhibited a measurable increase in facial anterior stain, compared to 35% of control users after six months; 15% of chlorhexidine gluconate users developed what was judged to be heavy stain, compared to 1% of control users after six months. Stain will be more pronounced in patients who have heavier accumulations of unremoved plaque. Stain resulting from use of Chlorhexidine Gluconate Oral Rinse, 0.12% does not adversely affect health of the gingivae or other oral tissues. Stain can be removed from most tooth surfaces by conventional professional prophylactic techniques. Additional time may be required to complete the prophylaxis. Discretion should be used when prescribing to patients with anterior facial restorations with rough surfaces or margins. If natural stain cannot be removed from these surfaces by a dental prophylaxis, patients should be excluded from Chlorhexidine Gluconate Oral Rinse, 0.12% treatment if permanent discoloration is unacceptable. Stain in these areas may be difficult to remove by dental prophylaxis and on rare occasions may necessitate replacement of these restorations.
3. Some patients may experience an alteration in taste perception while undergoing treatment with chlorhexidine gluconate oral rinse. Rare instances of permanent taste alteration following chlorhexidine gluconate oral rinse have been reported via post-marketing product surveillance.

Pregnancy

Teratogenic Effects

Pregnancy Category B

Reproduction studies have been performed in rats and rabbits at chlorhexidine gluconate doses up to 300 mg/kg/day and 40 mg/kg/day, respectively, and have not revealed evidence of harm to fetus. However, adequate and well-controlled studies in pregnant women have not been done. Because animal reproduction studies are not always predictive of human response, this drug should be used during pregnancy only if clearly needed.

Nursing Mothers

It is not known whether this drug is excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when Chlorhexidine Gluconate Oral Rinse, 0.12% is administered to nursing women.

In parturition and lactation studies with rats, no evidence of impaired parturition or of toxic effects to suckling pups was observed when chlorhexidine gluconate was administered to dams at doses that were over 100 times greater than that which would result from a person's ingesting 30 ml (2 capfuls) of chlorhexidine gluconate oral rinse, 0.12% per day.

Pediatric Use

Clinical effectiveness and safety of Chlorhexidine Gluconate Oral Rinse, 0.12% have not been established in children under the age of 18

Carcinogenesis, Mutagenesis, and Impairment of Fertility

In a drinking water study in rats, carcinogenic effects were not observed at doses up to 38 mg/kg/day. Mutagenic effects were not observed in two mammalian *in vivo* mutagenesis studies with chlorhexidine gluconate. The highest doses of chlorhexidine used in a mouse dominant-lethal assay and a hamster cytogenetics test were 1000 mg/kg/day and 250 mg/kg/day, respectively. No evidence of impaired fertility was observed in rats at doses up to 100 mg/kg/day.

ADVERSE REACTIONS

The most common side effects associated with chlorhexidine gluconate oral rinses are: 1) an increase in staining of teeth and other oral surfaces; 2) an increase in calculus formation; and 3) an alteration in taste perception, see **WARNINGS** and **PRECAUTIONS**. Oral irritation and local allergy-type symptoms have been spontaneously reported as side effects associated with use of chlorhexidine gluconate rinse.

The following oral mucosal side effects were reported during placebo-controlled adult clinical trials: aphthous ulcer, grossly obvious gingivitis, trauma, ulceration, erythema, desquamation, coated tongue, keratinization, geographic tongue, mucocele, and short frenum. Each occurred at a frequency of less than 1.0%. Among post marketing reports, the most frequently reported oral mucosal symptoms associated with chlorhexidine gluconate oral rinse, 0.12% are stomatitis, gingivitis, glossitis, ulcer, dry mouth, hypesthesia, glossal edema, and paresthesia.

Minor irritation and superficial desquamation of the oral mucosa have been noted in patients using chlorhexidine gluconate oral rinse, 0.12%.

There have been cases of parotid gland swelling and inflammation of the salivary glands (sialadentis) reported in patients using chlorhexidine gluconate oral rinse.

To report SUSPECTED ADVERSE REACTIONS, contact Hi-Tech Pharmacal Co., Inc. at 1-800-262-9010 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

OVERDOSAGE

Ingestion of 1 or 2 ounces of Chlorhexidine Gluconate Oral Rinse, 0.12% by a small child (~10 kg body weight) might result in gastric distress, including nausea, or signs of alcohol intoxication. Medical attention should be sought if more than 4 ounces of Chlorhexidine Gluconate Oral Rinse, 0.12% is ingested by a small child or if signs of alcohol intoxication develop.

DOSAGE AND ADMINISTRATION

Chlorhexidine Gluconate Oral Rinse, 0.12% therapy should be initiated directly following a dental prophylaxis. Patients using Chlorhexidine Gluconate Oral Rinse, 0.12% should be reevaluated and given a thorough prophylaxis at intervals no longer than six months.

Recommended use is twice daily oral rinsing for 30 seconds, morning and evening after toothbrushing. Usual dosage is 1/2 fl oz (marked in cup) of undiluted Chlorhexidine Gluconate Oral Rinse, 0.12%. Patients should be instructed to not rinse with water or other mouthwashes, brush teeth or eat immediately after using Chlorhexidine Gluconate Oral Rinse, 0.12%. Chlorhexidine Gluconate Oral Rinse, 0.12% is not intended for ingestion and should be expectorated after rinsing.

HOW SUPPLIED

Chlorhexidine Gluconate Oral Rinse, 0.12% is a blue, peppermint flavored liquid in:

A 16 fl oz (473 mL) amber plastic bottle with a child-resistant closure and dosage cup for consumer use, and in 15 mL unit dose cups.

It should be dispensed in original container or in amber glass.

Store above freezing 0°C (32°F).

Rx only

Manufactured by:
Hi-Tech
Pharmacal Co., Inc.
Amityville, NY 11701

Rev. 720:00 7/10
MG# 11387

PRINCIPAL DISPLAY PANEL - Kit Carton

HALYARD*

24-HOUR
ORAL CARE KIT
with BALLARD* Technology

Use
with
CHG
▼
CHG

with
H_2O_2

q2

1
HALYARD*
Prep
Pack

2
HALYARD*
Toothbrush
Packs

4

**HALYARD*
Suction Swab
Packs with H_2O_2**

6

**HALYARD*
Suction Swab Packs
with Alcohol-Free Mouthwash**

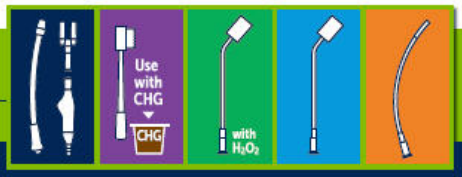
2

**HALYARD*
Suction Catheter
Packs**

HALYARD*

24-HOUR ORAL CARE KIT

with BALLARD* Technology



q2

HALYARD*

24-HOUR ORAL CARE KIT

with BALLARD* Technology

Use with CHG
CHG
with H_2O_2

q2

1 HALYARD* Prep Pack	2 HALYARD* Toothbrush Packs	4 HALYARD* Suction Swab Packs with H_2O_2	6 HALYARD* Suction Swab Packs with Alcohol-Free Mouthwash	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

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

NDC 69697-978-01

Product of Mexico and China

01-H1-065-0-00 / 70169514

REF 97012

Expiration Date

LOT

HALYARD*

24-HOUR ORAL CARE KIT

with BALLARD* Technology

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

Alcohol-Free Mouthwash Ingredients

Purified Water, Sorbitol, Glycerin, Flavor, Sodium Saccharin, FD&C Blue #1, FD&C Yellow #5, Cetylpyridinium Chloride, Benzoic Acid, Sodium Benzoate

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

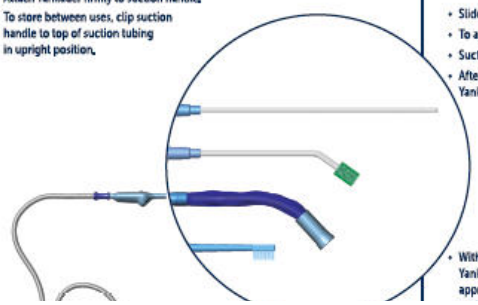
Purified Water, Glycerin, Flavor, Sodium Saccharin

Questions or Comments? 1-844-425-9273

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 suction handle firmly to suction canister tubing. Attach Y-adapter firmly to suction port. Then firmly attach oral care suction tubing to one Y-adapter port and closed suction tubing to the other port. (Use the Y-adapter only if using a single suction canister for both closed suctioning and oral care.)
- Attach Yankauer firmly to suction handle.
- To store between uses, clip suction handle to top of suction tubing in upright position.



Yankauer Assembly and Use

- Attach Yankauer firmly to suction handle.

- Slide cleaning sleeve toward suction 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

Toothbrush Pack with CHG Solution, Suction Swab Pack with H_2O_2 and Suction Swab Pack with Alcohol-Free Mouthwash Assembly and Use

Toothbrush or Suction Swab

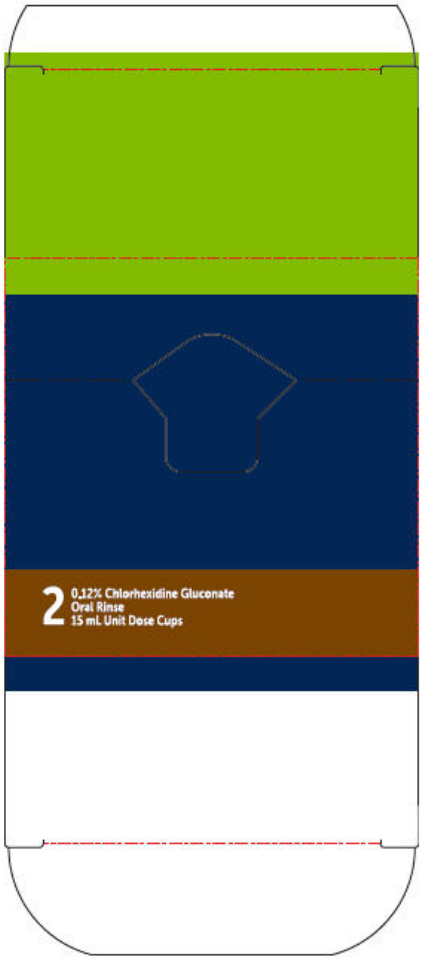
- Select **HALYARD® Toothbrush or Suction Swab** pack from kit and open package.
- Remove Yankauer from suction handle and set in component tray. Firmly attach tool.
- Peel back the appropriate solution dispenser lid and moisten tool†.
- To apply suction, slide switch to ON.
- Clean and suction oral cavity using appropriate tool according to hospital protocol.
- Slide switch to OFF.
- Remove tool from suction handle and discard.
- Reattach Yankauer firmly 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.

† For use of CHG Oral Rinse located in the side container, see product package insert. Four Suction Swab Packs with H_2O_2 provided for 24-hour period per Drug Facts.

Suction Catheter Pack Assembly and Use



Q2 ORAL CARE KIT WITH CHG

hydrogen peroxide and chlorhexidine gluconate kit

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:69697-982

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69697-982-01	1 in 1 CARTON		

Quantity of Parts		
Part #	**Package Quantity**	**Total Product Quantity**
Part 1	4 CUP, UNIT-DOSE	56 mL
Part 2	6 CUP, UNIT-DOSE	84 mL
Part 3	10 TUBE	100 g
Part 4	10 CUP, UNIT-DOSE	150 mL

Part 1 of 4

HYDROGEN PEROXIDE

hydrogen peroxide mouthwash

Product Information	
Item Code (Source)	NDC:69697-991
Route of Administration	ORAL

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: FV98Z8GITP)	
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	NDC:69697-991-01	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 4

ALCOHOL FREE MOUTHWASH

mouthwashes and breath fresheners (liquids and sprays) mouthwash

Product Information

Route of Administration	ORAL

Other Ingredients

Ingredient Kind	Ingredient Name	Quantity
INGR	**water** (UNII: 059QF0KO0R)	
INGR	**Benzoic Acid** (UNII: 8SKN0B0MIM)	
INGR	**Saccharin Sodium Dihydrate** (UNII: SB8ZUX40TY)	
INGR	**Sodium Benzoate** (UNII: OJ245FE5EU)	
INGR	**Glycerin** (UNII: PDC6A3C0OX)	
INGR	**Cetylpyridinium Chloride** (UNII: D9OM4SK49P)	
INGR	**D&C Green no. 5** (UNII: 8J6RDU8L9X)	
INGR	**Sorbitol** (UNII: 506T60A25R)	
INGR	**Mint** (UNII: FV98Z8GITP)	

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
Cosmetic		03/13/2008	

Part 3 of 4

MOUTH MOISTURIZER

other oral hygiene products unassigned

Product Information

Route of Administration	ORAL

Other Ingredients

Ingredient Kind	Ingredient Name	Quantity
INGR	**water** (UNII: 059QF0KO0R)	
INGR	**Xylitol** (UNII: VCQ006KQ1E)	
INGR	**Sodium Benzoate** (UNII: OJ245FE5EU)	
INGR	**Aloe Vera Leaf** (UNII: ZY81Z83H0X)	
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	

Part 4 of 4

CHLORHEXIDINE GLUCONATE

chlorhexidine gluconate rinse

Product Information

Item Code (Source)	NDC:50383-720
Route of Administration	ORAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength

Chlorhexidine Gluconate (UNII: MOR84MUD8E) (Chlorhexidine - UNII:R4KO0DY52L)	Chlorhexidine Gluconate	1.2 mg in 1 mL

Inactive Ingredients	
Ingredient Name	**Strength**
Alcohol (UNII: 3K9958V90M)	
FD&C Blue no. 1 (UNII: H3R47K3TBD)	
Glycerin (UNII: PDC6A3C0OX)	
PEG-40 sorbitan diisostearate (UNII: JL4CCU7I1G)	
Mint (UNII: FV98Z8GITP)	
Saccharin Sodium Dihydrate (UNII: SB8ZUX40TY)	
Water (UNII: 059QF0KO0R)	

Product Characteristics			
Color	BLUE	**Score**	
Shape		**Size**	
Flavor	PEPPERMINT	**Imprint Code**	
Contains			

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:50383-720-15	10 in 1 TRAY		
1		15 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
ANDA	ANDA074356	05/07/1996	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA074356	05/07/1996	

Labeler - Halyard Health (079617666)

Establishment

Name	Address	ID/FEI	Business Operations
Avent		049316284	LABEL(69697-982) , MANUFACTURE(69697-982) , PACK(69697-982)

Establishment

Name	Address	ID/FEI	Business Operations
Elba		108428483	MANUFACTURE(69697-982)

Establishment

Name	Address	ID/FEI	Business Operations
Hi Tech Pharmacal		101196749	MANUFACTURE(69697-982)

Revised: 1/2016 Halyard Health