

SHORT TERM ORAL CARE SYSTEM- hydrogen peroxide

Sage Products 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.

Short Term Oral Care System

Drug Facts

<i>Active ingredient</i>	<i>Purpose</i>
Hydrogen Peroxide 1.5%.....	Oral Debriding Agent

Use

Aids in the removal of secretions associated with sore mouth

Warnings

Do not use:

- For more than 7 days unless told to do so by a doctor.
- Avoid Swallowing.

Stop use and ask a doctor if:

- Sore mouth symptoms do not improve in 7 days.
- Swelling, rash or fever develops.
- Irritation, pain or redness persists or worsens.

Keep out of reach of children.

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

Directions

- Use up to 4 times daily or as directed by a dentist or doctor.
- Adults and children 3 years and over: rinse mouth for approx. one minute with 1/2 Tbsp. Instruct to expectorate.
- Children under 12 yeras of age: supervise use.
- Children under 3 years of age: consult a dentist or doctor.

Inactive Ingredients

Water, menthol flavor, polysorbate 80, phosphoric acid, sodium saccharin, Blue 1 (CI42090), Yellow 6 (CI15985)

Questions

Call toll free 800-323-2220

MADE IN U.S.A.

NOT MADE WITH NATURAL RUBBER LATEX

Short Term Oral Care System with Perox-A-Mint Solution



Short Term Oral Care System

with Perox-A-Mint® solution

For healthcare professional use only

Kit Directions

- Apply Sodium Bicarbonate Mouthpaste to Toothbrush.
- Brush teeth, tongue and gums (toothbrush can be made softer by placing it under warm water prior to use).
- Rinse mouth with Perox-A-Mint Solution as defined under Directions in Drug Facts for Perox-A-Mint solution below.
- Apply Mouth Moisturizer as needed.

Contents

- 1.5 fl. oz./44ml bottle of Perox-A-Mint solution.
- 0.5 oz./14g tube of Mouth Moisturizer.
- 0.3 oz./9g tube of Sodium Bicarbonate Mouthpaste.
- 1 Ultra-Soft Toothbrush.

Drug Facts

Active ingredient

Perox-A-Mint solution*:

Hydrogen peroxide 1.5% Oral debriding agent

Purpose

Use

Aids in the removal of secretions associated with sore mouth.

Warnings

Do not use:

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- Adults and children 3 years and over: rinse mouth for approx. one minute with 1/2 Tbsp. Instruct to expectorate.
- Children under 12 years of age: supervise use.
- Children under 3 years of age: consult a dentist or doctor.

Inactive ingredients

Water, menthol flavor, polysorbate 80, phosphoric acid, sodium saccharin, FD&C Blue #1, FD&C Yellow #6.

Questions or comments?

Call toll free 800-323-2220.

Sodium Bicarbonate Mouthpaste* ingredients

Sorbitol, calcium carbonate, sodium bicarbonate, water, sodium lauryl sulfate, cellulose gum, flavor, titanium dioxide, sodium saccharin, sodium benzoate, glycerin.

Mouth Moisturizer* ingredients

Water, coconut oil, xylitol, spearmint flavor, sodium carboxymethyl cellulose, tocopheryl acetate (vitamin E), spearmint oil, carbomer, polysorbate 20, polysorbate 80, potassium sorbate, cetylpyridinium chloride.

* Manufactured for Sage Products LLC

Reorder # 6002-D



Patents: www.sageproducts.com/patents

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Sage Products LLC

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www.sageproducts.com/canada

NPN 02242225

TOOTHETTE[®]
Oral Care

Perox-A-Mint[®]
Solution

Oral Debriding Agent

SAGE[®]
PRODUCTS INC.

R3674I 1.5 fl. oz./44 mL


Drug Facts	Purpose Oral Debriding Agent
Active ingredient Hydrogen Peroxide 1.5%.....	Use Aids in the removal of secretions associated with sore mouth
Warnings Do not use: • For more than 7 days unless told to do so by a doctor. • Avoid swallowing. Stop use and ask a doctor if: • Sore mouth symptoms do not improve in 7 days. • Swelling, rash or fever develops. • Irritation, pain or redness persists or worsens.	Directions • Use up to 4 times daily or as directed by a dentist or doctor. • Adults and children 3 years and over: rinse mouth for approx. one minute with 1/2 Tbsp. Instruct to expectorate. • Children under 12 years of age: supervise use. • Children under 3 years of age: consult a dentist or doctor.
Inactive ingredients Water, menthol flavor, polysorbate 80, phosphoric acid, sodium saccharin, Blue 1 (CI42090), Yellow 6 (CI15985)	Questions? Call toll free 800-323-2220

Sage Products, Inc.
3909 Three Oaks Road
Cary, IL 60013
800-323-2220
www.sageproducts.com

Reorder # 6065

*Pour la version française,
consulter le feuillet ci-joint*

In Canada, imported by:
Au Canada, importé par :
Cardinal Health Canada Inc.
Mississauga, ON L5T 1C2



6 1802918001813

SHORT TERM ORAL CARE SYSTEM
hydrogen peroxide kit

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:53462-024

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:53462-024-30	1 in 1 KIT; Type 1: Convenience Kit of Co-Package	10/19/2016	

Quantity of Parts		
Part #	Package Quantity	Total Product Quantity
Part 1	1 TUBE	9 g
Part 2	1 BOTTLE, PLASTIC	44 mL
Part 3	1 TUBE	14 g

Part 1 of 3
SODIUM BICARBONATE
other oral hygiene products

Product Information		
Other Ingredients		
Ingredient Kind	Ingredient Name	Quantity

INGR	SODIUM BICARBONATE (UNII: 8MDF5V39QO)	
INGR	CARBOXYMETHYLCELLULOSE SODIUM (UNII: K679OBS311)	
INGR	SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
INGR	SODIUM BENZOATE (UNII: OJ245FE5EU)	
INGR	WATER (UNII: 059QF0KO0R)	
INGR	SACCHARIN SODIUM (UNII: SB8ZUX40TY)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		1 in 1 KIT		
1		9 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
Cosmetic			

Part 2 of 3

PEROX-A-MINT SOLUTION

hydrogen peroxide mouthwash

Product Information

Item Code (Source)	NDC:53462-075
Route of Administration	BUCCAL

Active Ingredient/Active Moiety

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

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
PHOSPHORIC ACID (UNII: E4GA8884NN)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
FD&C BLUE NO. 1 (UNII: HBR47K3TBD)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		1 in 1 KIT		
1	NDC:53462-075-30	44 mL in 1 BOTTLE, PLASTIC; 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	05/21/1998	

Part 3 of 3

MOUTH MOISTURIZER

other oral hygiene products

Product Information

Other Ingredients

Ingredient Kind	Ingredient Name	Quantity
INGR	COCONUT OIL (UNII: Q9L0O73W7L)	
INGR	XYLITOL (UNII: VCQ006KQ1E)	
INGR	CARBOXYMETHYLCELLULOSE SODIUM (UNII: K679OBS311)	
INGR	.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
INGR	WATER (UNII: 059QF0KO0R)	
INGR	POLYSORBATE 20 (UNII: 7T1F30V5YH)	
INGR	POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
INGR	POTASSIUM SORBATE (UNII: 1VPU26JZZ4)	
INGR	CETYLPYRIDINIUM CHLORIDE (UNII: D9OM4SK49P)	
INGR	CARBOMER HOMOPOLYMER TYPE B (ALLYL PENTAERYTHRITOL CROSSLINKED) (UNII: HHT01ZNK31)	
INGR	SPEARMINT OIL (UNII: C3M81465G5)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		1 in 1 KIT		
1		14 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
Cosmetic			

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part356	10/19/2016	

Labeler - Sage Products LLC (054326178)

Registrant - Sage Products LLC (054326178)

Establishment

Name	Address	ID/FEI	Business Operations
Sage Products LLC		054326178	manufacture(53462-024, 53462-075)

Revised: 1/2019

Sage Products LLC