SUCTION SWAB SYSTEM WITH PEROX-A-MINT SOLUTION - SUCTION SWAB AND SUCTION TOOTHBRUSH- hydrogen peroxide SUCTION SWAB SYSTEM WITH PEROX-A-MINT SOLUTION - SUCTION SWAB-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.

Suction Swab System with Perox-A-Mint® Solution

Drug Facts

Suction Swab with Perox-A-Mint Solution

Active Ingredient: Purpose
PEROX-A-MINT:
Hydrogen Peroxide 1.5% Oral Debriding Agent

Uses

Suction Swab

• Aids in the removal of debris and secretions.

Suction Swab and Suction Toothbrush

• Aids in the removal of dental plaque, debris and secretions.

Warnings

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

Suction Swab

- Use as directed on individual packages
- Apply Mouth Moisturizer as needed.
- Discard after use.
- Suction Swabs and Applicator Swabs are intended for single oral use only.
- Use up to 4 times daily or as directed by a dentist or doctor.
- Children under 12 years of age: supervise use.
- Children under 3 years of age: consult a dentist or doctor.
- Use a bite block when performing oral care on patients with altered levels of consciousness or those who cannot comprehend commands.

• Ensure foam is intact after use. If not, remove any particles from oral cavity.

Suction Swab and Suction Toothbrush

- Use as directed on individual packages
- Apply Mouth Moisturizer as needed.
- Discard after use.
- Suction Toothbrushes, Suction Swabs and Applicator Swabs are intended for single oral use only.
- Use up to 4 times daily or as directed by a dentist or doctor.
- Children under 12 years of age: supervise use.
- Children under 3 years of age: consult a dentist or doctor.
- Use a bite block when performing oral care on patients with altered levels of consciousness or those who cannot comprehend commands.
- Ensure foam is intact after use. If not, remove any particles from oral cavity.

Inactive Ingredients

Water, menthol flavor, polysorbate 80, phosphoric acid, sodium saccharin, Blue 1 (CI 42090), Yellow 6 (CI 15985).

Questions? Call toll-free 800-323-2220.

Suction Swab System with Perox-A-Mint Solution - Suction Swab



MIHOTO Suction Swab System with Perox-A-Mint® solution

CONTENTS:

- 6 packages of 2 Suction Swabs with sodium bicarbonate and a .25 fl. oz./7ml pouch of Perox-A-Mint solution.
 10 Applicator Swabs.
 .5 oz./14g tube of Mouth Moisturizer.

Pour la version française, consulter le feuillet ci-inclus

Drug Facts

Active ingredient

Purpose

..Oral debriding agent

Perox-A-Mint solution* 1.5% Hydrogen peroxide.

Aids in the removal of debris and secretions.

Warnings

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.

- Use as directed on individual packages, Apply Mouth Moisturizer as needed,
- · Discard after use.
- Suction Swabs and Applicator Swabs are intended for single oral use only.
 Use up to 4 times daily or as directed by a dentist or doctor.
- Children under 12 years of age: supervise use
- Children under 3 years of age: consult a dentist or doctor.
- Use a bite block when performing oral care on patients with altered levels of consciousness or those who cannot comprehend commands.
 Ensure foam is intact after use. If not, remove any particles from oral cavity.

Inactive ingredients'

Water, menthol flavor (aroma), polysorbate 80, phosphoric acid, sodium saccharin, Blue 1 (CI 42090), Yellow 6 (CI 15985).

Questions or comments?

Call to free 800-323-2220.

Sodium Bicarbonate* ingredients

Water, sodium bicarbonate, sodium carboxymethyl cellulose, sodium lauryl sulfate, flavor (aroma), sodium saccharin, sodium benzoate.

Mouth Moisturizer ingredients

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

* Manufactured for Sage Products, Inc. U.S. Patent No. Des. 282,698; 5,151,094; 5,378,226 LATEX FREE • MADE IN U.S.A.

Reorder #6550

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NPN 02242225

Oral Care

SUCTION SWABS

with Perox-A-Mint® solution

For single use only

CONTENTS:

2 Suction Swabs with sodium bicarbonate 0.25 fl. oz./7mL Perox-A-Mint solution

Pour la version française, consulter le feuillet ci-inclus

Drug Facts

Active ingredient PEROX-A-MINT SOLUTION*:

Ophridina Agent

Purpose

Hydrogen peroxide 1.5%Oral Debriding Agent

Uses

Aids in the removal of debris and secretions.

Warnings

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

- Before opening, turn package over, burst solution packet with thumbs.
- Peel lid to open.
- Remove Suction Swab and attach to suction line.
- Clean teeth and oral cavity for approximately 1 minute.
- To suction, place thumb over port.
- Repeat cleaning with other Suction Swab as needed.
- To clear tubing, rinse with sterile saline or appropriate solution.
- Discard after use.
- Use up to 4 times daily, or as directed by a dentist or doctor.
- Children under 12 years of age: supervise use.
- Children under 3 years of age: consult a dentist

or aoctor.

- Use a bite block when performing oral care on patients with altered levels of consciousness or those who cannot comprehend commands.
- Ensure foam is intact after use. If not, remove any particles from oral cavity.

Inactive ingredients

Water, menthol flavor (aroma), polysorbate 80, phosphoric acid, sodium saccharin, Blue 1 (Cl 42090), Yellow 6 (Cl 15985).

Questions? Call toll-free 800-323-2220.

Sodium Bicarbonate ingredients*: Water, sodium bicarbonate, sodium carboxymethyl cellulose, sodium lauryl sulfate, flavor, sodium saccharin, sodium benzoate.

* Manufactured for Sage Products LLC

NOT MADE WITH NATURAL RUBBER LATEX
MADE IN U.S.A.

Reorder #6512



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

Patents: www.sageproducts.com/patents

35216



|W||He||e Suction Swab System

with Perox-A-Mint® solution

CONTENTS:

- 6 packages of 2 Suction Swabs with sodium bicarbonate and a .25 fl. oz./7ml pouch of Perox-A-Mint solution
- 2 packages of 1 Suction Toothbrush with sodium bicarbonate and a .25 fl. oz./7ml pouch of Perox-A-Mint solution
- 10 Applicator Swabs
- .5 oz./14g tube of Mouth Moisturizer

Pour la version française, consulter le feuillet ci-inclus

Drug Facts

Active ingredient PEROX-A-MINT SOLUTION: 1.5% Hydrogen peroxide.......

Purpose

.....Oral debriding agent

Aids in the removal of dental plague, debris and secretions.

Warnings

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 as directed on individual packages.
- Apply Mouth Moisturizer as needed.
- Discard after use.
- Suction Toothbrushes. Suction Swabs and Applicator Swabs are intended for single oral use only.
- Use up to 4 times daily or as directed by a dentist or doctor.
- Children under 12 years of age: supervise use. Children under 3 years of age: consult a dentist or doctor.
- Use a bitle block when performing oral care on patients with altered levels of consciousness or those who cannot comprehend commands. Ensure foam is intact after use. If not, remove any particles from oral cavity.

Inactive ingredients

Water, menthol flavor (aroma), polysorbate 80, phosphoric acid, sodium saccharin, Blue 1 (CI 42090), Yellow 6 (CI 15985).

Questions or comments?

Cal to free 800-323-2220.

Sodium Bicarbonate ingredients:

Water, sodium bicarbonate, sodium carboxymethyl cellulose, sodium lauryl sulfate, flavor (aroma), sodium saccharin, sodium benzoate.

Mouth Moisturizer ingredients*:

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



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Reorder #6552

* Manufactured for Sage Products, Inc. Covered under one or more of the following U.S. Patent Numbers: D282,698; 5,151,094; 5,378,226 In Canada, imported by/Au Canada, importé par : Cardinal Health Canada Inc. • Mississauga, ON L5T 1C2



LATEX FREE





NPN 02242225

SUCTION TOOTHBRUSH

With Perox-A-Mint® solution

For single use only

CONTENTS:

1 Suction Toothbrush with sodium bicarbonate 0.25 fl. oz./7mL Perox-A-Mint solution

Pour la version française, consulter le feuillet ci-inclus

Drug Facts

Active ingredient

Purpose

PEROX-A-MINT SOLUTION*: Hydrogen peroxide 1.5%Oral Debriding Agent

Hooo

Aids in the removal of dental plaque, debris and secretions.

Warnings

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

- Before opening, turn package over, burst solution packet with thumbs,
- · Peel lid to open.
- · Remove Toothbrush and attach to suction line.
- Clean teeth and oral cavity for approximately 1 minute.
- To suction, place thumb over port.
- To clear tubing, rinse with sterile saline or appropriate solution.
- Discard after use.
- Use up to 4 times daily, or as directed by a dentist or doctor.
- Children under 12 years of age: supervise use.
- Children under 3 years of age: consult a dentist or doctor-
- Use a bite block when performing oral care on patients with altered levels of consciousness or those who cannot comprehend commands.
- Ensure foam is intact after use. If not, remove any particles from oral cavity.

Inactive ingredients

Water, menthol flavor, polysorbate 80, phosphoric acid, sodium saccharin, Blue 1 (CI 42090), Yellow 6 (CI 15985).

Questions? Cal toll-free 800-323-2220.

Sodium Bicarbonate ingredients*: Water, sodium bicarbonate, sodium carboxymethyl cellulose, sodium lauryl sulfate, flavor, sodium saccharin, sodium benzoate.

Manufactured for Sage Products LLC

NOT MADE WITH NATURAL RUBBER LATEX



SUCTION SWAB SYSTEM WITH PEROX-A-MINT SOLUTION - SUCTION SWAB AND SUCTION TOOTHBRUSH

hydrogen peroxide kit

Product Information

Product Type HUMAN OTC DRUG Item Code (Source) NDC:53462-553

Packaging

	#	Item Code	Package Description	Marketing Start Date	Marketing End Date
ı	1	NDC:53462-553-60	1 in 1 KIT; Type 1: Convenience Kit of Co-Package	06/30/2007	

Quantity of Parts

A	Quantity of 2 and		
Part #	Package Quantity	Total Product Quantity	
Part 1	1 TUBE	14 g	
Part 2		1	
Part 3	8 PACKET	56 mL	

Part 1 of 3

MOUTH MOISTURIZER

other oral hygiene products

Product Information

Other Ingred	Other Ingredients				
Ingredient Kind	Ingredient Name	Quantity			
INGR	COCONUT OIL (UNII: Q9L0O73W7L)				
INGR	XYLITOL (UNII: VCQ006KQ1E)				
INGR	CARBO XYMETHYLCELLULO SE SODIUM (UNII: K679 OBS 311)				
INGR	.ALPHATO CO PHERO L ACETATE (UNII: 9E8X80D2L0)				
INGR	WATER (UNII: 059QF0KO0R)				
INGR	POLYSORBATE 20 (UNII: 7T1F30 V5YH)				
INGR	POLYSORBATE 80 (UNII: 6 OZP39 ZG8 H)				
INGR	POTASSIUM SORBATE (UNII: 1VPU26JZZ4)				
INGR	CETYLPYRIDINIUM CHLORIDE (UNII: D9 OM4SK49P)				
INGR	CARBO MER HO MO POLYMER TYPE B (ALLYL PENTAERYTHRITOL CROSSLINKED) (UNII: HHT0 1ZNK31)				
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				

Part 2 of 3

SODIUM BICARBONATE

other oral hygiene products

Product Information

Other Ingredients		
Ingredient Kind	Ingredient Name	Quantity
INGR	SODIUM BICARBONATE (UNII: 8 MDF5 V39 QO)	
INGR	CARBOXYMETHYLCELLULOSE SODIUM (UNII: K679OBS311)	
INGR	SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
INGR	SODIUM BENZOATE (UNII: OJ245FE5EU)	
INGR	WATER (UNII: 059QF0KO0R)	
INGR	SACCHARIN SODIUM (UNII: SB8 ZUX40 TY)	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
Cosmetic			

Part 3 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		
HYDRO GEN PERO XIDE (UNII: BBX060AN9V) (HYDROGEN PERO XIDE - UNII:BBX060AN9V)	HYDROGEN PEROXIDE	15 mg in 1 mL		

Inactive Ingredients		
Ingredient Name	Strength	
WATER (UNII: 059QF0KO0R)		
POLYSORBATE 80 (UNII: 6OZP39ZG8H)		
PHO SPHO RIC ACID (UNII: E4GA8884NN)		
SACCHARIN SO DIUM (UNII: SB8 ZUX40 TY)		
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)		
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)		

P	Packaging					
#	Item Code	Package Description	Marketing Start Date	Marketing End Date		
1		8 in 1 KIT				
1		7 mL in 1 PACKET; 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		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part356	06/30/2007	

SUCTION SWAB SYSTEM WITH PEROX-A-MINT SOLUTION - SUCTION SWAB

hydrogen peroxide kit

Product Information

Product Type HUMAN OTC DRUG Item Code (Source) NDC:53462-650

Packaging

	# Item Code	Package Description	Marketing Start Date	Marketing End Date
ı	1 NDC:53462-650-60	1 in 1 KIT; Type 1: Convenience Kit of Co-Package	06/28/2002	

Quantity of Parts

Quantity of Farts			
Part #	Package Quantity	Total Product Quantity	
Part 1	1 TUBE	14 g	
Part 2		1	
Part 3	6 PACKET	42 mL	

Part 1 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	CARBO XYMETHYLCELLULO SE SODIUM (UNII: K679 OBS 311)	
INGR	.ALPHATO COPHEROL 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: D9 OM4SK49 P)	
INGR	CARBO MER HOMO POLYMER TYPE B (ALLYL PENTAERYTHRITOL CROSSLINKED) (UNII: HHT0 1ZNK31)	
INGR	SPEARMINT OIL (UNII: C3M8 146 5G5)	

P	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			

Part 2 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: K679 OBS 311)		
INGR	SODIUM LAURYL SULFATE (UNII: 368GB5141J)		
INGR	SODIUM BENZOATE (UNII: OJ245FE5EU)		
INGR	WATER (UNII: 059QF0KO0R)		
INGR	SACCHARIN SODIUM (UNII: SB8ZUX40TY)		

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
Cosmetic			

Part 3 of 3

PEROX-A-MINT SOLUTION

hydrogen peroxide mouthwash

Item Code (Source) NDC:53462-075

Active Ingredient/Active Moiety Ingredient Name

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

Inactive Ingredients			
Ingredient Name	Strength		
WATER (UNII: 059QF0KO0R)			
POLYSORBATE 80 (UNII: 6 OZP39 ZG8 H)			
PHO SPHO RIC ACID (UNII: E4GA8884NN)			
SACCHARIN SODIUM (UNII: SB8ZUX40TY)			
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)			

]	Packaging							
7	# Item Code	Package Description	Marketing Start Date	Marketing End Date				
:	L	6 in 1 KIT						
:	L	7 mL in 1 PACKET; 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				

Marketing Information								
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date					
OTC monograph not final	part356	06/28/2002						

Labeler - Sage Products LLC (054326178)

FD&C YELLOW NO. 6 (UNII: H77VEI93A8)

Registrant - Sage Products LLC (054326178)

Revised: 1/2019 Sage Products LLC