SUCTION TOOTHBRUSH WITH PEROX-A-MINT SOLUTION- 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 Toothbrush with Perox-A-Mint Solution

Drug Facts

Active Ingredients	Purpose
Perox-A-Mint Solution	
Hydrogen peroxide 1.5%	Oral Debriding Agent

Uses

• 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 Toothbrush with Perox-A-Mint Solution and Mouth Moisturizer

- **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 Applicator Swab to apply Mouth Moisturizer as needed.
- 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

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Sodium Bicarbonate ingredients*: Water, sodium bicarbonate, sodium carboxymethyl cellulose, sodium lauryl sulfate, flavor, 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 LLC

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

Reorder #6572

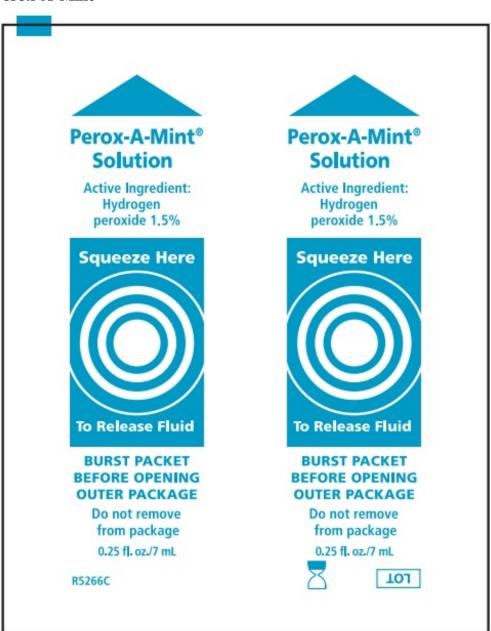


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In Canada, imported by/Au Canada, importé par : Cardinal Health Canada Inc. • Mississauga, ON L5T 1C2



Perox-A-Mint



SUCTION TOOTHBRUSH WITH PEROX-A-MINT SOLUTION

hydrogen peroxide kit

Product Information

Product Type HUMAN OTC DRUG Item Code (Source) NDC:53462-572

Packaging
Packaging

l	# Item Code	Package Description	Marketing Start Date	Marketing End Date
ı	1 NDC:53462-572-60	1 in 1 KIT; Type 1: Convenience Kit of Co-Package	06/30/2003	

Quantity of Parts

Part #	Package Quantity	Total Product Quantity
Part 1		1
Part 2	1 PACKET	7 mL
Part 3	1 PACKET	2 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: K679 OBS 311)	
INGR	SODIUM LAURYL SULFATE (UNII: 368 GB5141J)	
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 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		
HYDRO GEN PERO XIDE (UNII: BBX060AN9V) (HYDRO GEN 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 SO DIUM (UNII: SB8ZUX40TY)		
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)		
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:53462-075-60	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	

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	CARBO XYMETHYLCELLULO SE SODIUM (UNII: K679 OBS 311)	
INGR	.ALPHATOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
INGR	WATER (UNII: 059QF0KO0R)	
INGR	POLYSORBATE 20 (UNII: 7T1F30V5YH)	
INGR	POLYSORBATE 80 (UNII: 6 O ZP39 ZG8 H)	
INGR	POTASSIUM SORBATE (UNII: 1VPU26JZZ4)	
INGR	CETYLPYRIDINIUM CHLORIDE (UNII: D9 OM4SK49 P)	
INGR	CARBOMER HOMOPOLYMER TYPE B (ALLYL PENTAERYTHRITOL CROSSLINKED) (UNII: HHT01ZNK31)	
INGR	SPEARMINT OIL (UNII: C3M81465G5)	

P	Packaging						
#	Item Code	Package Description	Marketing Start Date	Marketing End Date			
1		2 g in 1 PACKET; 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	06/30/2003					

Labeler - Sage Products, LLC (054326178)

Revised: 9/2019 Sage Products, LLC