

**TOOTHETTE ORAL CARE SINGLE USE SYSTEM WITH ANTISEPTIC ORAL RINSE-
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.

Toothette Oral Care Single Use System

Drug Facts

<i>Active ingredient:</i>	<i>Purpose</i>
ANTISEPTIC ORAL RINSE*: Cetylpyridinium chloride .05%	Antiseptic Rinse

Uses

- Helps reduce the chance of infection in minor oral irritation.
- Aids in the removal of debris.

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 antiseptis 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.
- Clean teeth and oral cavity for approximately one minute.
- Instruct to expectorate.
- Repeat cleaning with other swab as needed.
- 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, sorbitol, peppermint flavor, potassium sorbate, polysorbate 80, polysorbate 20, citric acid, FD&C Blue No. 1.

Questions?

Call toll-free 800-323-2220.

LATEX FREE • FOR SINGLE USE ONLY • MADE IN U.S.A.

* Manufactured for Sage Products LLC

Toothette Oral Care Single Use System with Antiseptic Oral Rinse

NDC 53462-120-60

▲ Peel Here ▲

DIN 02243571

TOOTHETTE
Oral Care

Single Use System with Antiseptic Oral Rinse

CONTENTS: 2 Toothette Plus Untreated Swabs
.25 fl oz / 7ml Antiseptic Oral Rinse

Pour la version française, consulter le feuillet ci-inclus

Drug Facts

Active ingredient	Purpose
ANTISEPTIC ORAL RINSE*: Cetylpyridinium chloride .05%.....	Antiseptic Rinse

Uses

- Helps reduce the chance of infection in minor oral irritation.
- Aids in the removal of debris.

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 antiseptics 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.
 - Clean teeth and oral cavity for approximately one minute.
 - Instruct to expectorate.
 - Repeat cleaning with other swab as needed.
 - 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, sorbitol, peppermint flavor, potassium sorbate.

polysorbate 80, polysorbate 20, citric acid, FD&C Blue No. 1.

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

LATEX FREE • FOR SINGLE USE ONLY • MADE IN U.S.A.

SAGE[®]
PRODUCTS

3909 Three Oaks Road • Cary, Illinois 60013
www.sageproducts.com • 800-323-2220

Reorder # 6120

* Manufactured for Sage Products LLC

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



TOOTHETTE ORAL CARE SINGLE USE SYSTEM WITH ANTISEPTIC ORAL RINSE

hydrogen peroxide kit

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:53462-120
--------------	----------------	--------------------	---------------

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:53462-120-60	1 in 1 KIT		

Quantity of Parts

Part #	Package Quantity	Total Product Quantity
--------	------------------	------------------------

Part 1 1 POUCH 7 mL

Part 1 of 1

ANTISEPTIC ORAL RINSE

cetylpyridinium chloride mouthwash

Product Information

Route of Administration BUCCAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
CETYLPYRIDINIUM CHLORIDE (UNII: D9OM4SK49P) (CETYLPYRIDINIUM - UNII:CUB7JI0JV3)	CETYLPYRIDINIUM CHLORIDE	.5 [iU] in 1 mL

Inactive Ingredients

Ingredient Name	Strength
SORBITOL (UNII: 506T60A25R)	
PEPPERMINT (UNII: V95R5KMY2B)	
POTASSIUM SORBATE (UNII: 1VPU26JZZ4)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
POLYSORBATE 20 (UNII: 7T1F30V5YH)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
WATER (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		1 in 1 PACKAGE		
1		2 in 1 PACKET		
1		7 mL in 1 POUCH		

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	03/31/2013	

Labeler - Sage Products LLC (054326178)

Registrant - Sage Products LLC (054326178)

Establishment

Name	Address	ID/FEI	Business Operations
Sage Products LLC		054326178	MANUFACTURE(53462-120)

Revised: 5/2014

Sage Products LLC