

PREOPERATIVE CARE

Sage® 2% Chlorhexidine Gluconate Cloths

Patient Preoperative Skin Preparation



NDC 053462-705

SAGE
PRODUCTS INC

2% CHLORHEXIDINE GLUCONATE* CLOTH

PATIENT PREOPERATIVE SKIN PREPARATION

* equivalent to 500mg chlorhexidine gluconate per cloth

NON-STERILE

Provides rapid bactericidal action
against a broad spectrum of microorganisms

Significantly reduces the number
of microorganisms on intact skin

Demonstrates continued antimicrobial
activity for up to 6 hours after application

Alcohol free — Rinse free
For external use only — Single use

2 DISPOSABLE CLOTHS
7.5 in x 7.5 in (19.1 cm x 19.1 cm)

DO NOT MICROWAVE



2%
chlorhexidine
gluconate

SAGE
PRODUCTS INC

Simple Interventions. Extraordinary Outcomes.



THE #1 SOURCE OF SURGICAL SITE INFECTION— BACTERIA ALREADY ON THE PATIENTS' SKIN

Endogenous flora can lead to surgical site infection (SSI) - one of the most common healthcare-acquired infections (HAIs).¹ This bacteria can include methicillin-resistant *S. aureus* (MRSA), vancomycin-resistant enterococci (VRE) and *Acinetobacter*. The skin is a major reservoir for bacteria, and it's crucial to prep skin before surgery to address risk of surgical site infection (SSI).

SSI RISK FACTORS²

PATIENT:

- Age
- Nutritional status
- Diabetes
- Nicotine use
- Obesity
- Coexistent infection at remote site
- Colonization with microorganisms

HOSPITAL:

- Inappropriate use of antibiotic prophylaxis
- Infection at remote site not treated before surgery
- Shaving vs. clipping
- Improper skin preparation

THE #1 THREAT TO SURGICAL PATIENTS: SURGICAL SITE INFECTION

Surgical site infections (SSIs) are the second most common healthcare-acquired infection¹ and one of the most costly.¹ Approximately 60 million inpatient and ambulatory surgical procedures are performed in the U.S. every year.^{3,4} Of those, surgical site infections (SSIs) occur after 2.6% to 5% of them.^{3,5} That amounts to 1.5 million SSIs annually.⁶ SSIs can also add 7-10 days to a patient's length of stay¹ and significantly increase costs⁴ and mortality risk.⁷



SSIs - A COSTLY PROBLEM

FINANCIAL COSTS:

- SSIs are the #1 most costly healthcare-acquired infection (HAI), costing hospitals more than \$7 billion a year.¹
- Each SSI can increase costs by an average of \$25,546.⁵ That rises to more than \$90,000 for MRSA infection.⁵
- The Centers for Medicare and Medicaid Services (CMS) no longer reimburses hospitals for certain SSIs, including mediastinitis.⁸

HUMAN COST:⁷

- Twice as likely to die
- 60% more likely to spend time in an ICU
- Over 5 times more likely to be readmitted

*A study of elderly patients found SSI due to *S. aureus* was responsible for more than a 5-fold increase in mortality⁹ and another study shows MRSA in a surgical wound resulted in over a 12-fold increase in mortality.¹⁰*

REFERENCES: 1. Scott, D. The Direct Medical Costs of Healthcare-Associated Infection in US Hospitals and the Benefits of Prevention. Division of Healthcare Quality Promotion National Center for Preparedness, Detection, and Control of Infectious Diseases Coordinating Center for Infectious Diseases Centers for Disease Control and Prevention March 2009. 2. Mangram AJ, et al., Guideline for prevention of surgical site infection, 1999. Centers for Disease Control and Prevention, Hospital Infection Control Practices Advisory Committee, Atlanta GA. 3. DeFrances CJ, Hall MJ, Podgornik MN, 2003 National hospital discharge survey. CDC, National Center for Health Statistics, Advance Data from Vital and Health Statistics. No. 359;8 July 2005:14. 4. Hall MJ, Lawrence L, Ambulatory surgery in the United States, 1996. CDC, National Center for Health Statistics, Advance Data from Vital and Health Statistics. No. 300;12Aug1998:7. 5. Stone PW, et al., Am J Infect Control. Nov 2005;33(9):501-9. 6. Figure calculated by multiplying SSI rate from ref #1 by procedures numbers from ref #3 and #4. 7. Kirkland KB, et al., Infect Control Hosp Epidemiol. Nov 1999;20(11):722-4. 8. Federal Register, Vol. 72 No.162, 2007 Aug; 47201-47205. 9. McGarry SA et al., Infect Control Hosp Epidemiol; June 2004; 25(6): 461-7. 10. Engermann JJ, et al., Clin Infect Dis. 1 Mar 2003;36(5):592-8.

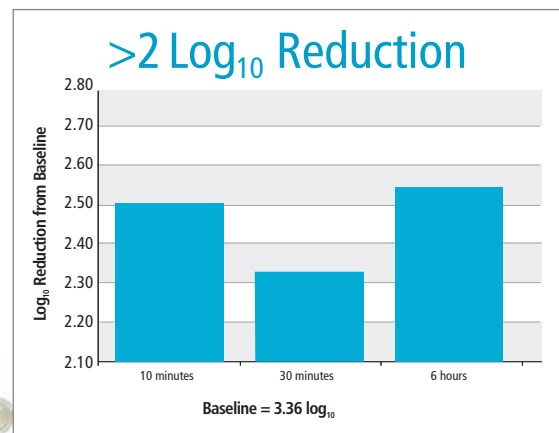
SAGE® 2% CHLORHEDXIDINE GLUCONATE (CHG) CLOTHS

THE FIRST FDA-APPROVED PREOPERATIVE SKIN PREP IN A CLOTH

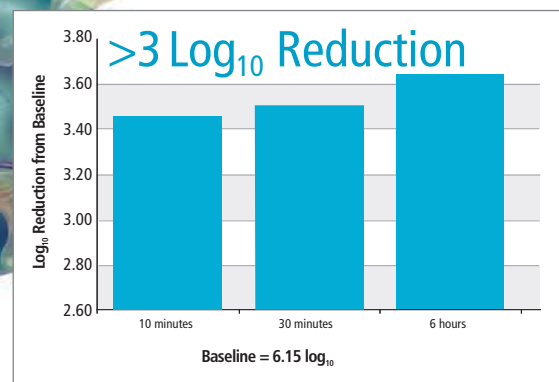
Sage 2% CHG Cloths address multidrug resistant organisms (MDROs) on the patients' skin – a known risk factor for SSIs.¹ Sage's innovative rinse-free, alcohol-free formula is designed for early preop prep. It stays on the skin for maximum persistence. The cloth consistently delivers a uniform dose of CHG, unlike other soaps and solutions.

2% FORMULA PROVEN EFFECTIVE

- Effective against broad spectrum of MDROs, including MRSA, VRE and *Acinetobacter*.^{2,3}
- Recognized by CDC as having "excellent" activity against gram-positive bacteria as well as "excellent" residual activity.¹



Sage 2% CHG Cloths to the Abdominal Site²



Sage 2% CHG Cloths to the Inguinal Site²

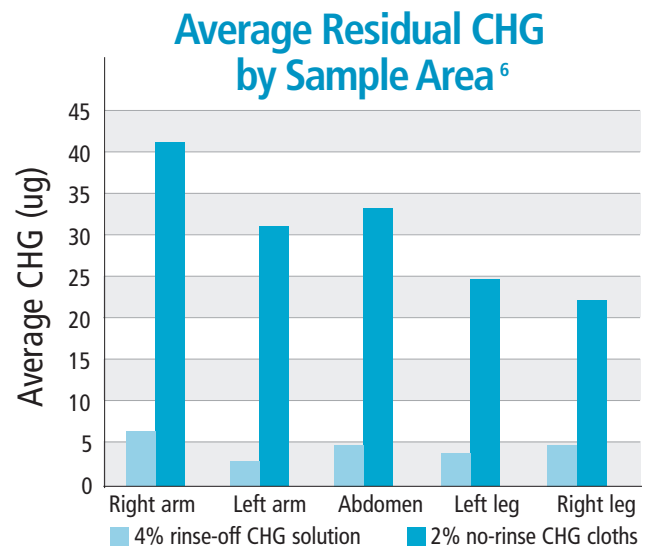
EFFECTIVE AGAINST PREVALENT SSI-CAUSING PATHOGENS^{2,*}

GRAM-POSITIVE PATHOGEN	SAGE 2% CHG CLOTH
<i>Staphylococcus aureus</i> (including MRSA)	✓
<i>Enterococcus faecalis & faecium</i> (including VRE)	✓
Coagulase-negative staphylococci	✓
<i>Streptococcus pneumoniae & pyogenes</i>	✓
Various other gram-positive aerobes	✓
GRAM-NEGATIVE PATHOGEN	
<i>Acinetobacter baumannii</i>	✓
<i>Bacteroides fragilis</i>	✓
<i>Enterobacter aerogenes</i>	✓
<i>Escherichia coli</i>	✓
<i>Klebsiella pneumoniae</i>	✓
<i>Proteus mirabilis</i>	✓
<i>Pseudomonas aeruginosa</i>	✓
<i>Serratia marcescens</i>	✓
FUNGI	
<i>Candida albicans</i>	✓

* In vitro testing.

A NO-RINSE 2% CHG CLOTH BETTER THAN 4% SOAP

- One study shows microbial counts were significantly less for areas treated with the no-rinse 2% CHG cloth compared with the traditional 4% CHG solution.⁴
- Use of no-rinse 2% CHG cloths resulted in considerably higher skin concentrations than 4% solution, with no gaps in antiseptic coverage⁵
- Another study found the amount of CHG that remains on the skin after application of no-rinse 2% CHG cloths is significantly higher than a 4% CHG that is rinsed off.⁶ [SEE GRAPH BELOW](#)



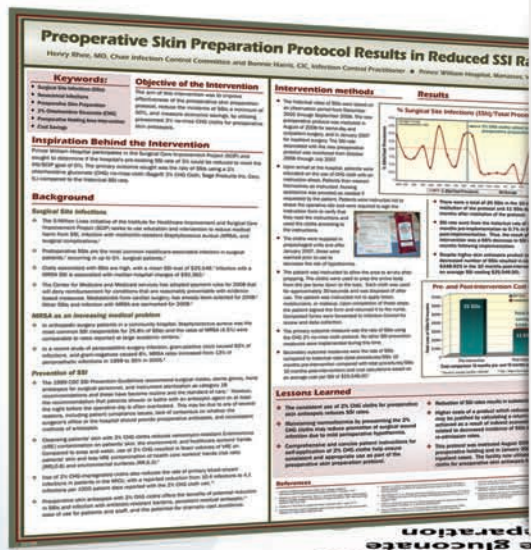
“The 2% CHG-impregnated cloth appears to be a practical and effective product for inpatient and outpatient settings.”⁷

REFERENCES: 1. Mangram AJ, et al., Guideline for prevention of surgical site infection, 1999. Centers for Disease Control and Prevention, Hospital Infection Control Practices Advisory Committee, Atlanta GA. 2. Time Kill and MIC Testing conducted by an independent laboratory, data on file. 3. Testing conducted by an independent laboratory, data on file. 4. Edmiston CE, et al., Skin antiseptics: efficacy of innovative chlorhexidine-impregnated surgical skin wipe (CIV) compared to traditional chlorhexidine surgical prep (TCP). Abstract presented at Surgical Infection Society (SIS) Annual Meeting, April 2006. 5. Edmiston CE, et al., Comparative of a new and innovative 2% chlorhexidine gluconate-impregnated cloth with 4% chlorhexidine gluconate as topical antiseptic for preparation of the skin prior to surgery. American Journal of Infection Control(AJIC). Mar 2007;35(2):89-96. 6. Ryder M, Improving Skin Antiseptics: 2% No-Rinse CHG Cloths Improve Antiseptic Persistence on Patient Skin Over 4% CHG Rinse-Off Solution. Poster presented at Association for Professionals in Infection Control and Epidemiology (APIC) June 2007. 7. O'Malley, P. Chlorhexidine Wipes: The New Weapon Against Surgical Site Infections? Clinical Nurse Specialist, 22(2):53-56. Mar/Apr 2008.

CLINICALLY PROVEN

Sage® 2% CHG Cloths have been proven effective time and again by articles in peer-reviewed journals and clinical poster presentations.

- A study published in the Journal of Arthroplasty shows Sage 2% CHG Cloths' effectiveness and compliance. The study noted an SSI rate of zero for patients prepped with the Sage 2% CHG cloths, compared to a 1.6% SSI rate for those not prepped with the cloths.¹
- In a clinical poster presented at the Institute for Healthcare Improvement (IHI) annual conference, one facility saw a 66% reduction in SSI over a 10-month period using Sage 2% CHG Cloths.²
- Another poster presented at the Association for Professionals in Infection Control and Epidemiology (APIC) annual conference showed one facility's SSI rate drop to zero 12 months after adding Sage 2% CHG Cloths to their prep protocol.³
- A second poster from APIC also reveals Sage 2% CHG Cloths' effectiveness and compliance. A facility saw a 50% SSI reduction among orthopedic surgical patients, and found the ease of use helped drive patient compliance.⁴



PROFESSIONALLY ACCEPTED

The use of Sage 2% CHG Cloths as part of a surgical site infection prevention program is being cited by professional organizations across the healthcare industry.

CDC RECOMMENDATIONS FOR PREVENTION OF SURGICAL SITE INFECTION⁵

7. Require patients to shower or bathe with an antiseptic agent on at least the night before the operative day. *Category IB[†]*

[†] *Category IB - Strongly recommended for implementation and supported by some experimental, clinical, or epidemiological studies and strong theoretical rationale.*

SHEA COMPENDIUM OF STRATEGIES TO PREVENT HEALTHCARE-ASSOCIATED INFECTION IN ACUTE CARE HOSPITALS⁶

"To gain maximum antiseptic effect of chlorhexidine, it must be allowed to dry completely and not be washed off."

AORN GUIDELINES FOR PREOPERATIVE SKIN ANTISEPSIS⁷

"Patients undergoing open class I surgical procedures below the chin should have two (2) preoperative showers with chlorhexidine gluconate (CHG) before surgery, when appropriate."

APIC GUIDE TO THE ELIMINATION OF ORTHOPEDIC SSI⁸

"A rinse-free CHG Cloth has been introduced as an alternative to CHG showers, and some data suggest ease of use and improved patient compliance as well as reduces rates of SSI."

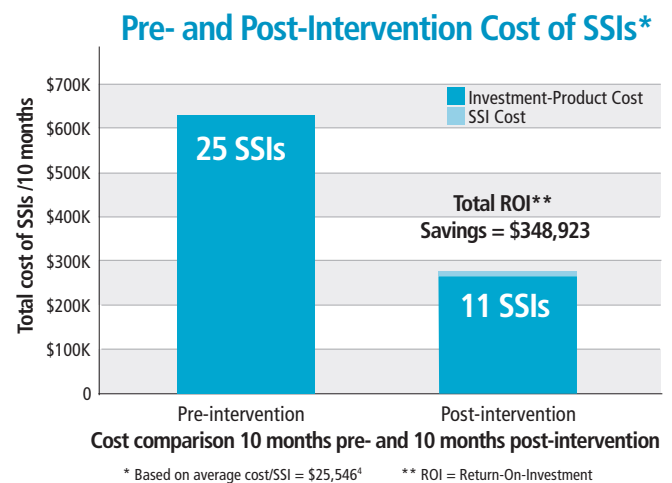
REFERENCES: 1. Johnson, et al., Preoperative Chlorhexidine Preparation and the Incidence of Surgical Site Infections After Hip Arthroplasty. *Journal of Arthroplasty*, April 2010. 2. Rhee H, Harris B, Preoperative Skin Preparation Protocol Results in Reduced SSI Rates. Presented at Institute for Healthcare Improvement (IHI), Orlando, FL, December 2007. 3. Livingston B, Challenges and Experience with Implementing Patient Preoperative Skin Preparation in a Veterans Administration (VA) Health System to Prevent Surgical Site Infections. Poster presented at Association for Professionals in Infection Control and Epidemiology (APIC) June 2007. 4. Eiselt D, Presurgical Skin Preparation with a Novel 2% Chlorhexidine Gluconate (CHG) Cloth Leads to Decrease in Surgical Site Infection Rates in Orthopedic Surgical Patients. Poster presented at Association for Professionals in Infection Control and Epidemiology (APIC) June 2007. 5. Mangram AJ, et al., Guideline for prevention of surgical site infection, 1999. Centers for Disease Control and Prevention, Hospital Infection Control Practices Advisory Committee, Atlanta GA. 6. Society for Healthcare Epidemiology of America, Oct 2008, Vol 29, Supplement 1, S58. 7. Perioperative Standards and Recommended Practices, Association of periOperative Registered Nurses (AORN), 2008, 537-555. 8. Guide to the Elimination of Orthopedic Surgical Site Infections. Association for Professionals in Infection Control and Epidemiology (APIC), 2010. 9. Bailey R, et al., Economic Value of Dispensing Home-Based Preoperative Chlorhexidine Bathing Cloths to Prevent Surgical Site Infection. *Infection Control and Hospital Epidemiology*, 32(5)465-471.

COST EFFECTIVE

The return on investment by using Sage 2% CHG Cloths has been proven in numerous articles and clinical posters.

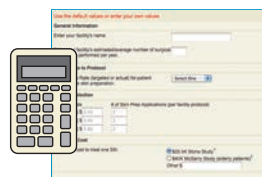
■ A recent study published in *Infection Control and Hospital Epidemiology (ICHE)* finds the Sage 2% CHG Cloth to be extremely cost-effective for routine distribution, saying "...this intervention remains cost-effective over a wide range of cloth efficacy and patient compliance values."⁹

■ A clinical poster presented at IHI showed one facility realized a cost avoidance of \$349,000 over a 10 month period using Sage 2% CHG Cloths.² **SEE GRAPH BELOW**



Stop Surgical Site Infections (SSI) – Opportunity Calculator

This unique tool estimates the number of SSIs that need to be eliminated in order to determine the break-even point for the routine use of Sage 2% CHG Cloths prior to surgery.



Once the break-even costs are calculated, you will see the financial savings for each additional SSI that is avoided.

See the positive financial impact Sage 2% CHG Cloths can have in your facility!

Visit: www.sageproducts.com/education/CHGCostJustStart.cfm

SAGE® 2% CHG CLOTHS ADDRESS MULTIDRUG RESISTANT ORGANISMS ON YOUR PATIENT'S SKIN PRIOR TO SURGERY

Our skin-friendly cloths are easy to use and deliver a uniform dose of CHG to the area being prepped. Fast-acting, broad-spectrum and alcohol-free, the 2% CHG stays on the skin to help prevent infection.

FDA approved 2% CHG formula

- Persistent - Rinse-free formula stays active for 6 hours after application.
- Cleans and moisturizes with surfactants and humectants.
- Proven to reduce drug-resistant MRSA and *Acinetobacter* by 99.9%.¹
- Alcohol-free formula won't dry out skin and reduces flammability risk.
- Active in the presence of blood and other organic matter.

FDA approved applicator cloth

- Easier for patient with impaired mobility.
- Replaces bottled solutions rinsed off in shower.
- Easier to prep skin folds and body contours.
- Delivers a uniform dose (500mg of CHG in each cloth) of CHG to the skin.
- Nonabrasive, textured cloth removes debris, allowing CHG to thoroughly cover prep area.
- No drips, runs or pooling.



* In vitro testing

REFERENCES: 1. DeBaun B, New Alcohol-Free 2% CHG Solution Reduced Bacterial Counts of Drug-Resistant Acinetobacter and MRSA by 99.9%. Poster presented at the 2007 Association of periOperative Registered Nurses (ADORN) Congress, Orlando, FL Mar 2007.

SAGE® 2% CHG CLOTHS PLUS 3M™ PERIDEX™ CHG ORAL RINSE SKIN ANTISEPSIS & ORAL CLEANSING PRIOR TO SURGERY

This preoperative kit combining Sage® 2% CHG Cloths and 3M™ Peridex™ 0.12% Chlorhexidine Gluconate (CHG) Oral Rinse helps address infection risk factors prior to surgery. Use the night before and morning of surgery as part of your preoperative infection prevention efforts.

The oral cavity is another reservoir for bacteria and a proven source of hospital-acquired pneumonias (HAPs).^{1,2} Bacteria that cause nosocomial respiratory disease colonize the oropharyngeal area, including dental plaque.^{3,4,5} These pathogens can be aspirated into the lungs and cause infection.⁵



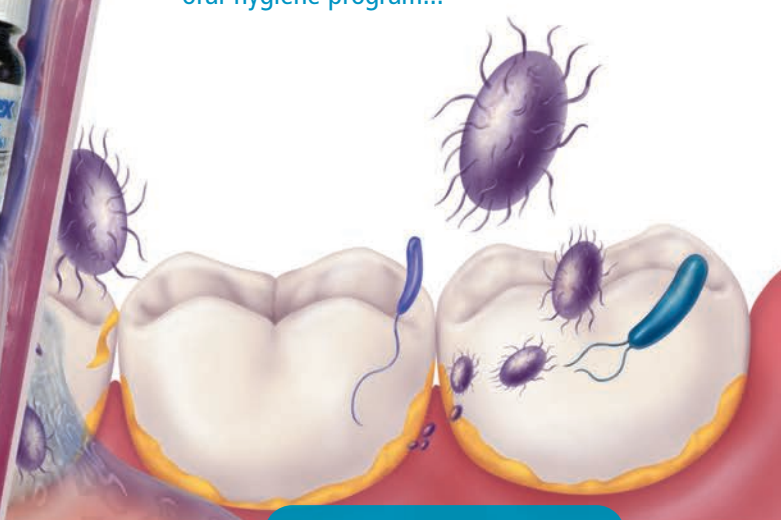
3M™ Peridex™ 0.12% CHG Oral Rinse:

- Convenient single dose bottle.
- Effective against gingivitis—a risk factor for other infections.
- Ultra-Soft Toothbrush contains nylon bristles to gently remove plaque, debris and oral secretions.



CDC GUIDELINES FOR PREVENTING HEALTHCARE-ASSOCIATED PNEUMONIA

“...Develop and implement a comprehensive oral-hygiene program...”²



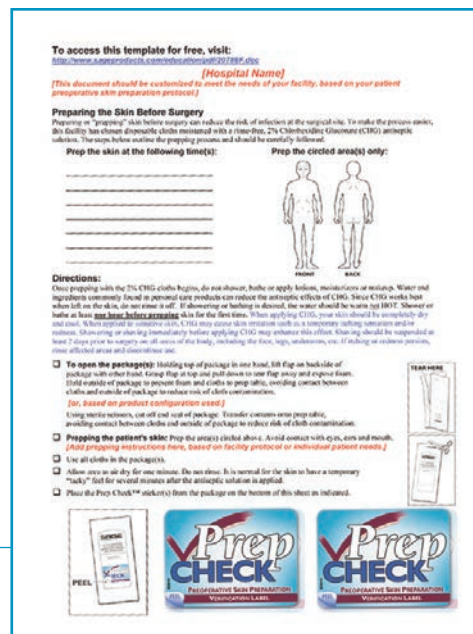
0.12% CHG Oral Rinse and toothbrush helps remove dental plaque and provides antimicrobial activity during oral rinsing.

REFERENCES: 1. Schleder B, et al., J Advocate Health Care. 2002 Spr/Sum;4(1):27-30. 2. Tablan OC, et al., Guidelines for preventing health-care—associated pneumonia, 2003, Recommendations of CDC and Healthcare Infection Control Practices Advisory Committee (HICPAC), 2003. 3. Scannapieco FA, J Periodontology. 1999 Jul;70(7):793-802. 4. Scannapieco FA, et al., Crit Care Med. 1992 Jun;20(6):740-5. 5. Fournier F, et al., Crit Care Med. 1998;26:301-8.

COMPLIANCE

The Prep Check™ label found on each package of Sage® 2% CHG Cloths is an easy to use tool to help verify a patient's skin has been prepped according to your facility's protocol. It helps take the guesswork out of vital steps to reduce potentially harmful skin microorganisms before surgery.

- Peel-and-stick label helps notify staff that a patient's skin has been prepped.
- Complements patient preop skin prep procedures for any hospital.
- Helps improve skin prep compliance by increasing awareness.
- Helps improve communication between caregiver and patient.
- Enhances documentation procedures.



TEMPLATE SUPPORT

Download our customizable template, then tailor it to make Prep Check part of your protocol for scheduled surgical procedures.

Our free template can help you implement skin prep verification at your facility.

Download at:
www.sageproducts.com/education/chgTemplate.asp

PRODUCT ORDERING:



SAGE® 2% CHLORHEXIDINE GLUCONATE CLOTHS*

*Equivalent to 500mg. chlorhexidine gluconate per cloth.

2 cloths per package
cloth size: 7.5" x 7.5"

96 packages/case
Reorder #9705

2 cloths per package
cloth size: 7.5" x 7.5"

48 packages/case
Reorder #9706



SAGE® 2% CHLORHEXIDINE GLUCONATE CLOTHS*

*Equivalent to 500mg. chlorhexidine gluconate per cloth.

3 individually wrapped packages
(2 cloths per package); cloth size: 7.5" x 7.5"

32 packages/case
Reorder #9707



PREOPERATIVE CHG KIT

3 2-packs of 2% Chlorhexidine Gluconate (CHG) Cloths

1 Package containing:
1 Unit Dose Container of 3M™ Peridex™
0.12% Chlorhexidine Gluconate (CHG)
Oral Rinse
1 Ultra-Soft Toothbrush
1 Untreated Swab

20 systems/case
Reorder #9001



CHLORHEXIDINE GLUCONATE (0.12%) ORAL RINSE

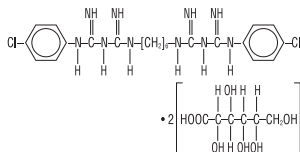
NDC 48878-0620-4

INGREDIENTS: 0.12% chlorhexidine gluconate in a base containing water, 11.6% alcohol, glycerin, PEG-40 sorbitan diostearate, flavor, sodium saccharin, and FD&C Blue No. 1.

Rx only

KEEP OUT OF REACH OF CHILDREN
0.5 fl oz (15ml)

DESCRIPTION: Peridex™ is an oral rinse containing 0.12% chlorhexidine gluconate (1,11-hexamethylene bis[5-(p-chlorophenyl) biguanide] di-D-gluconate) in a base containing water, 11.6% alcohol, glycerin, PEG-40 sorbitan diostearate, flavor, sodium saccharin, and FD&C Blue No. 1. Peridex™ Oral Rinse is a near-neutral solution (pH range 5-7). Chlorhexidine gluconate is a salt of chlorhexidine and gluconic acid. Its chemical structure is:



CLINICAL PHARMACOLOGY: Peridex™ Oral Rinse provides antimicrobial activity during oral rinsing. The clinical significance of Peridex™ Oral Rinse's antimicrobial 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 Peridex™ 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 Peridex™ Oral Rinse 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 Peridex™ 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 in 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 300mg 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.

INDICATION: Peridex™ Oral Rinse 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. Peridex™ Oral Rinse has not been tested among patients with acute necrotizing ulcerative gingivitis (ANUG). For patients having coexisting gingivitis and periodontitis, see PRECAUTIONS.

CONTRAINDICATIONS: Peridex™ Oral Rinse should not be used by persons who are known to be hypersensitive to chlorhexidine gluconate or other formula ingredients.

WARNINGS: The effect of Peridex™ Oral Rinse on periodontitis has not been determined. An increase in supragingival calculus was noted in clinical testing in Peridex™ Oral Rinse users compared with control users. It is not known if Peridex™ Oral Rinse 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 Peridex™ Oral Rinse should not be used as a major indicator of underlying periodontitis.

2. Peridex™ Oral Rinse 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 tooth staining. In clinical testing, 56% of Peridex™ Oral Rinse users exhibited a measurable increase in facial anterior stain, compared to 35% of control users after six months; 15% of Peridex™ Oral Rinse 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 Peridex™ Oral Rinse does not adversely affect health of the gingivae or other oral tissues. Stain can be removed from most tooth surfaces by conventional 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 Peridex™ Oral Rinse 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 Peridex™ Oral Rinse. Rare instances of permanent taste alteration following Peridex™ Oral Rinse use 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 300mg/kg/day and 40mg/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 Peridex™ Oral Rinse 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 30ml of Peridex™ Oral Rinse per day.

PEDIATRIC USE: Clinical effectiveness and safety of Peridex™ Oral Rinse 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 38mg/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 100mg/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 ulcers; grossly obvious gingivitis; trauma; ulceration; erythema; desquamation; coated tongue; keratinization; geographic tongue; mucocoele; 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 Peridex™ Oral Rinse are stomatitis, gingivitis, glossitis, ulcer, dry mouth, hyperthemia, glossal edema, and parosthesia.

Minor irritation and superficial desquamation of the oral mucosa have been noted in patients using Peridex™ Oral Rinse.

There have been cases of parotid gland swelling and inflammation of the salivary glands (sialadenitis) reported in patients using Peridex™ Oral Rinse.

OVERDOSAGE: Ingestion of 1 or 2 ounces of Peridex™ Oral Rinse 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 Peridex™ Oral Rinse is ingested by a small child or if signs of alcohol intoxication develop.

DOSAGE AND ADMINISTRATION: Peridex™ Oral Rinse therapy should be initiated directly following a dental prophylaxis. Patients using Peridex™ Oral Rinse 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 15 mL of undiluted Peridex™ Oral Rinse. Patients should be instructed to not rinse with water, or other mouthwashes, brush teeth, or eat immediately after using Peridex™ Oral Rinse. Peridex™ Oral Rinse is not intended for ingestion and should be expectorated after rinsing.

HOW SUPPLIED: Peridex™ Oral Rinse is supplied as a blue liquid in single dose amber plastic bottles with child-resistant dispensing closures. Store above freezing (32°F or 0°C).

Rx only.

DIRECTIONS FOR USE: Swish in mouth undiluted for 30 seconds, then spit out. Use after breakfast and before bedtime, or use as prescribed.

NOTE: To minimize medicinal taste, do not rinse with water immediately after use.

To open, press down while turning cap. To reseal, turn cap past "clicks" until tightly locked.

WHAT TO EXPECT WHEN USING PERIDEX™ ORAL RINSE

Your dentist has prescribed Peridex™ Oral Rinse to treat your gingivitis, to help reduce the redness and swelling of your gums, and also to help you control any gum bleeding. Use Peridex™ Oral Rinse regularly, as directed by your dentist, in addition to daily brushing. Spit out after use. Peridex™ Oral Rinse should not be swallowed.

Peridex™ Oral Rinse may cause some tooth discoloration, or increase in tartar (calculus) formation, particularly in areas where stain and tartar usually form. It is important to see your dentist for removal of any stain or tartar at least every six months or more frequently if your dentist advises.

- Both stain and tartar can be removed by your dentist or hygienist. Peridex™ Oral Rinse may cause permanent discoloration of some front-tooth fillings.
- To minimize discoloration, you should brush and floss daily, emphasizing areas which begin to discolor.
- Local hypersensitivity and sometimes generalized allergic reactions have also been reported. Peridex™ Oral Rinse should not be used by persons who have a sensitivity to it or its components.
- Peridex™ Oral Rinse may taste bitter to some patients and can affect how foods and beverages taste. This will become less noticeable in most cases with continued use of Peridex™ Oral Rinse.
- To avoid taste interference, rinse with Peridex™ Oral Rinse after meals.

Do not rinse with water or other mouthwashes immediately after rinsing with Peridex™ Oral Rinse.

If you have any questions or comments about Peridex™ Oral Rinse, contact your dentist or pharmacist.

STORE ABOVE FREEZING (32°F OR 0°C)

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Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

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