safety

Anasept® Antimicrobial Skin and Wound Gel has been subjected to rigorous safety and toxicological evaluations to comply with FDA regulations at an independent FDA registered testing facility and shown to meet all criteria for safe use.

- Modified Skin Irritation Study(FSHA method 7 day exposure with repeated insult to intact and abraded skin)
- Cytotoxicity (USP method)
- Systemic Toxicity (USP method)
- ISO Sensitization Study.

Test reports available upon written request.

clinically tested:

Anasept® Antimicrobial Skin & Wound Cleanser, the liquid version of Anasept Antimicrobial Skin & Wound Gel is clinically proven to reduce wound bioburden levels and improve the rate of healing.*

Anasept® is also available as Anasept Antimicrobial Skin & Wound Cleanser in a wide-variety of dispensers specifically designed for skin & wound cleansing applications. Anasept Antimicrobial Skin & Wound Cleanser has all the same powerful broad spectrum antimicrobial and safety features inherent in Anasept Antimicrobial Skin & Wound Gel.

Anasept products are manufactured in the USA.

EXTERNAL USE ONLY.
NOT FOR OPTHALMIC USE.

latex FREE

ANACAPA TECHNOLOGIES

DIRECTIONS FOR USE:

Wound Care:

1) Debride wound, if necessary or cleanse wound with a wound cleanser such as Anasept® Antimicrobial Skin and Wound Cleanser.
2) Apply a generous amount (1/4 " to 1/2 "thick) of Anasept Antimicrobial Skin and Wound Gel to entire wound bed, including areas of undermining.
3) Apply a thin coating to peri-wound skin area and allow to dry.
4) Cover with appropriate wound dressing or covering (avoid silver and other wound dressings containing heavy metals).
5) Change dressing once a day. Maintain a moist wound environment between dressing changes.

NOTE: Anasept products contain sodium chloride which is not compatible with wound care products that contain silver. Silver in the presence of sodium chloride will be converted to insoluble silver chloride and become inactive.

Indwelling Vascular Catheters:

1) Apply sufficient quantity of Anasept Antimicrobial Skin & Wound Gel to completely cover skin area around the indwelling vascular catheter.
2) Cover with appropriate site dressing.

Ostomy:

1) Apply a thin coating of Anasept Antimicrobial Skin & Wound Gel to peri-stomal area.
2) Allow to dry.
3) Apply Ostomy appliance.

Skin Care:

1) Cleanse affected area with appropriate skin cleanser.
2) Allow to dry.
3) Apply a thin coating of Anasept Antimicrobial Skin & Wound Gel.
4) Reapply as necessary.

Ordering Information

Anasept® Antimicrobial Skin and Wound Gel

Catalog No.	NDC Number	Size	Case Quantity
5003G	67180-500-03	3oz	12

Medicare Reimbursement Code: HCPCS #A6248

301 E. Arrow Hwy, Ste. 106
San Dimas, California 91773
Toll-Free: 800-489-2591
Tel: 909-394-7795
Fax: 909-394-9895
e-mail: anacapa@anacapa-tech.net
Website: www.anacapa-tech.net

ANASEPT® ANTIMICROBIAL SKIN AND WOUND GEL

The clear, safe and most effective choice for skin and wound antisepsis™

Kills all bacteria, fungi, viruses and spores without harming healthy tissue

anasept® GEL

KILLS MRSA & VRE IN 60 SECONDS

product description:

Anasept® Antimicrobial Skin and Wound Gel is an extremely safe topical hydrogel with exceptionally rapid broad spectrum bactericidal, including the antibiotic resistant strains MRSA & VRE, fungicidal, virucidal and sporicidal properties through the action of sodium hypochlorite. There is no known microbial resistance to Anasept Antimicrobial Skin & Wound Gel.

Anasept® Antimicrobial Skin and Wound Gel is pure, completely colorless, isotonic, non-cytotoxic, tissue compatible viscous hydrogel. Anasept Antimicrobial Skin & Wound Gel has a 3 year shelf-life when stored at normal room temperature up to 25° C (77° F).

time kill studies:

Extremely high concentrations of pathogenic micro-organisms were exposed to Anasept Antimicrobial Skin and Wound Gel over the course of precisely timed intervals in the presence of an interfering substance that simulates the organic load conditions of the wound environment and is know to inhibit the action of antimicrobial agents. Anasept Antimicrobial Skin and Wound Gel proved 100% effective against all pathogenic micro-organisms tested within the first ten minutes of application except for Acinetobacter baumannii where it was shown to be 99.998% effctive in the same test period (see tables).

TIME KILL STUDIES

Test Organisms: Table of Antimicrobial Activity

Pathogenic Bacteria:	Initial Organism	Exposure Time/% Kill			
	Count	1 min.	3 min.	5 min.	10 min.
Escherichia coli	10^7	99.25%	99.986%	99.9995%	100%
Staphylococcus aureus	10^7	100%	100%	100%	100%
Methicillin Resistant Staphylococcus aureus (MRSA)	10^7	100%	100%	100%	100%
Vancomycin Resistant Enterococcus faecalis (VRE)	10^7	100%	100%	100%	100%
Pseudomonas aeruginosa	10^7	99.996%	100%	100%	100%
Proteus mirabilis	10^7	99.888%	99.998%	99.9998%	100%
Serratia marcescens	10^7	100%	100%	100%	100%
Acinetobacter baumannii	10^7	99.722%	99.977%	99.996%	99.998%
Clostridium difficile	10^5	100%	100%	100%	100%
Pathogenic Fungi:					
Candida albicans	10^6	100%	100%	100%	100%
Aspergillus niger	10^6	100%	100%	100%	100%

TIME KILL STUDIES

Test Organism: Table of Sporicidal Activity

Test Substance	Initial Microrganism Count/ML	Exposure Time	Percent Reduction	Log Reduction
Clostridium difficile - spore	10^6	15 minutes	99.986%	>4.0

indications for use:

Anasept® Gel is intended for OTC use for management of skin abrasions, minor irritations, lacerations, cuts, exit sites and intact skin.

Professional Use:
Anasept® Gel is intended to be used under the supervision of a healthcare professional in the management of wounds such as stage I-IV pressure ulcers, partial & full thickness wounds, diabetic foot & leg ulcers, post surgical wounds, first & second degree burns, grafted & donor sites.

24 hour challenge test:

Anasept Antimicrobial Skin and Wound Gel was subjected to a high concentration of pathogenic micro-organisms (amount known to cause infection) in the presence of an interfering substance that simulates the organic load of the wound and is known to inactivate the antimicrobial agents. The duration of antimicrobial effectiveness of Anasept Antimicrobial Skin and Wound Gel was determined in a re-challenge of the original test sample with a high concentration of freshly prepared micro-organisms after 24 hours of initial exposure to pathogenic micro-organisms.

Sustained duration of action:

Anasept Antimicrobial Skin and Wound Gel was shown to maintain microbiocidal activity even after 24 hours and repeated exposure to pathogenic micro-organisms in the simulated wound environment. The gel reduced all pathogenic test organisms by more than 99% within the first fifteen minutes of repeated exposure.

TIME KILL STUDIES - 24 HOUR CHALLENGE:

Test Organisms: Table of Antimicrobial Activity

Pathogenic Bacteria:	Initial Organism Ct. / Re-challenge Organism Ct	Exposure time after re-challenge at 24 hours / % Kill		
		5 min.	10 min.	15 min.
Escherichia coli	10^7 / 10^7	71.25%	96.63%	99.49%
Staphylococcus aureus	10^7 / 10^7	95.91%	96.45%	99.16%
Methicillin Resistant Staphylococcus aureus (MRSA)	10^7 / 10^7	95.69%	99.38%	99.78%
Vancomycin Resistant Enterococcus faecalis (VRE)	10^7 / 10^7	92.8%	96.9%	99.61%
Pseudomonas aeruginosa	10^7 / 10^7	84.35%	98%	99.88%
Proteus mirabilis	10^7 / 10^7	67.14%	97.71%	99.74%
Serratia marcescens	10^7 / 10^7	96%	99.36%	99.94%
Acinetobacter baumannii	10^7 / 10^7	13.64%	85.25%	99.25%
Pathogenic Fungi:				
Candida albicans	10^6 / 10^6	98.89%	99.99%	99.9996%
Mix of all above including Candida albicans	10^7 / 10^7	88.75%	97.31%	99.8%

*J. Lindfors. A Comparison of an Antimicrobial Wound Cleanser to Normal Saline in Reduction of Bioburden and its Effect on Wound Healing. Ostomy / Wound Management 2004; 50 (8): 28-41.

Website: www.anacapa-tech.net