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



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 CRE, 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 2 year shelf-life when stored at normal room temperature up to 25° C (77° F).

time kill studies:

Extremely high concentrations of pathogenic microorganisms 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

Pathogenic Bacteria

Acinetobacter baumanni Carbapenem Resistant E. Clostridium difficile Escherichia coli Methicillin Resistant Staph Proteus mirabilis Pseudomonas aeruginosa Serratia marcescens Staphylococcus aureus Vancomycin Resistant Ent Pathogenic Fungi: Aspergillus niger

TIME KILL STUDIES

Test Organism

Candida albicans

Clostridium difficile - spo



indications for use:

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

Anasept Gel is 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.

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

KILLS MRSA & VRE IN 60 SECONDS

24 hour challenge test:

GEL

anasepy

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.

Acinetobacter baumannii Escherichia coli Methicillin Resistant Staph Proteus mirabilis Pseudomonas aeruginosa Serratia marcescens Staphylococcus aureus Vancomycin Resistant Ent Pathogenic Fungi: Candida albicans Mix of all above including

Pathogenic Bacteria:

Website: www.anacapa-tech.net

Test Organisms: Table of Antimicrobial Activity

a:	Initial Organism		Exposure Ti	me/% Kill	
	Count	l min.	3 min.	5 min.	10 min.
i	107	99.722%	99.977%	99.996%	99.998%
. coli (CRE)	106	99.999%	99.999%	99.999%	99.999%
	105	100%	100%	100%	100%
	107	99.25%	99.986%	99.9995%	100%
hylococcus aureus (MRSA)	107	100%	100%	100%	100%
	107	99.888%	99.998%	99.9998%	100%
1	I 0 ⁷	99.996%	100%	100%	100%
	107	100%	100%	100%	100%
	I 0 ⁷	100%	100%	100%	100%
terococcus faecalis (VRE)	107	100%	100%	100%	100%
	I 0 ⁶	100%	100%	100%	100%
	I 0 ⁶	100%	100%	100%	100%

Test Organism: Table of Sporicidal Activity

	Initial Microrganism	Exposure	Percent	Log
	Count/ML	Time	Reduction	Reduction
ore	I 0 ⁶	15 minutes	99.986%	>4.0



TIME KILL STUDIES - 24 HOUR CHALLENGE: Test Organisms: Table of Antimicrobial Activity

	Initial Organism Ct. /	Exposure time after re-challenge		
	Re-challenge Organism Ct	at 24 hours / % Kill		
		5 min.	10 min.	15 min.
i	107 / 107	13.64%	85.25%	99.25%
	107 / 107	71.25%	96.63%	99.49%
hylococcus aureus (MRSA)	107 / 107	95.69%	99.38%	99.78%
	107 / 107	67.14%	97.71%	99.74%
1	107 / 107	84.35%	98%	99.88%
	107 / 107	96%	99.36%	99.94%
	107 / 107	95.91%	96.45%	99.16%
terococcus faecalis (VRE)	107 / 107	92.8%	96.9%	99.61%
	106 / 106	98.89%	99.99%	99.9996%
g Candida albicans	107 / 107	88.75%	97.31%	99.8%

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.
- ISO Vaginal Irritation Study

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® is a registered trademark of Anacapa Technologies, Inc.

Anasept products are manufactured in the USA.

EXTERNAL USE ONLY. NOT FOR OPTHALMIC USE.

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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:

- I) 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:

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

Skin Care:

- I) 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		
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Medicare Reimbursement Code: HCPCS #A6248

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