

anasept[®]

ANTIMICROBIAL SKIN & WOUND CLEANSER



Anasept[®] Antimicrobial Skin and Wound Cleanser is a clear, isotonic liquid that helps in the mechanical removal of the debris and foreign material from the application site, by the action of the fluid (Wound Cleanser) moving across the wound bed or application site. Anasept Antimicrobial Skin and Wound Cleanser contains a broad-spectrum antimicrobial agent sodium hypochlorite. It inhibits the growth of bacteria such as *Acinetobacter baumannii*, *Clostridium difficile*, *Escherichia coli*, *Proteus mirabilis*, *Pseudomonas aeruginosa*, *Serratia marcescens*, *Staphylococcus aureus*, including antibiotic resistant strains, such as *Carbapenem Resistant E. Coli (CRE)*, *Methicillin Resistant Staphylococcus aureus (MRSA)* and *Vancomycin resistant Enterococcus faecalis (VRE)* that are commonly found in wound bed, as well as fungi, such as *Aspergillus niger*, *Candida albicans*, and *Candida auris*.

Anasept is a very pure, completely colorless, isotonic, tissue compatible solution. Anasept is stable for 2 years from date of manufacture, when stored at normal room temperature up to 25°C (77°F) and is free of necrotizing chemicals such as sodium hydroxide. Anasept is stable up to 14 weeks after initial use.

INDICATIONS FOR USE

OTC USE:

Anasept is intended for OTC use for mechanical cleansing and removal of dirt, debris and foreign material from skin abrasions, lacerations, minor irritations, cuts, exit sites and intact skin.

PROFESSIONAL USE:

Anasept is intended for use under the supervision of a healthcare professional for cleansing of foreign materials, including microorganisms from wounds such as stage I-IV pressure ulcers, diabetic foot ulcers, post-surgical wounds, first and second degree burns, grafted and donor sites.

SAFETY:

Anasept has been subjected to rigorous safety testing at an independent laboratory and shown to meet the criteria for safe use.

- Modified Primary Skin Irritation (FHSA method - 7 day exposure with repeated insult to intact and abraded skin)
- Cytotoxicity (ISO Agarose Overlay method)
- Systemic toxicity (ISO Acute Systemic Toxicity)
- ISO Sensitization Study

CLINICALLY TESTED: Anasept[®] is clinically proven to reduce wound bioburden levels and improve the rate of healing.*

In the time kill studies below, extremely high concentrations of pathogenic microorganisms were exposed to Anasept over the course of precisely timed intervals in the presence of an interfering substance that simulated the organic load condition of the wound environment and is known to inhibit the action of antimicrobial agents.

TIME KILL STUDIES FOR ANASEPT ANTIMICROBIAL SKIN AND WOUND CLEANSER

TABLE OF MICROBIAL ACTIVITY				
Test Organisms:	Initial Microorganism Count/ML	Exposure time / % Kill		
Pathogenic Bacteria		30 seconds	1 minute	5 minutes
Acinetobacter baumannii	10 ⁷	-	99.089%	99.98%
Carbapenem Resistant E. coli (CRE)	10 ⁶	99.999%	99.999%	99.999%
Clostridium difficile	10 ⁵	100%	100%	100%
Escherichia coli	10 ⁷	100%	100%	100%
Methicillin Resistant Staphylococcus aureus (MRSA)	10 ⁷	100%	100%	100%
Proteus mirabilis	10 ⁸	99.998%	100%	100%
Pseudomonas aeruginosa	10 ⁷	100%	100%	100%
Serratia marcescens	10 ⁷	100%	100%	100%
Staphylococcus aureus	10 ⁷	100%	100%	100%
Vancomycin Resistant Enterococcus faecalis (VRE)	10 ⁷	100%	100%	100%
Pathogenic Fungi				
Aspergillus niger	10 ⁷	99.99%	99.9999%	100%
Candida albicans	10 ⁷	99.1%	99.9%	100%
Candida auris	10 ⁵	99.1%	>99.9%	>99.9%

TABLE OF SPORICIDAL ACTIVITY				
Test Spore	Initial Spore Count/ML	Exposure Time	Percent Reduction	Log Reduction
Clostridium difficile - spore	10 ⁶	15 minutes	99.999%	>5.7

TABLE OF VIRUCIDAL ACTIVITY				
Test Virus	Initial Virus Count/ML	Exposure Time	Percent Reduction	Log Reduction
HIV-Type 1 (Human Immuno Deficiency Virus)	10 ⁶	5 minutes	99.997%	≥4.5
SARS Related Coronavirus 2	10 ^{5.25}	5 minutes	≥99.98%	≥3.75
Human Coronavirus Strain 229E	10 ^{5.5}	5 minutes	≥99.99%	≥4.0

ORDERING INFORMATION

Anasept® Antimicrobial Skin & Wound Cleanser				
CATALOG NO.		NDC NUMBER	SIZE	CASE QUANTITY
4004C	(Dispensing Cap)	67180-400-04	4 oz	24
4008C	(Dispensing Cap)	67180-400-08	8 oz	12
4004SC	(Sprayer)	67180-400-44	4 oz	12
4008SC	(Sprayer)	67180-400-88	8 oz	12
4008TC	(Trigger Sprayer)	67180-408-88	8 oz	12
4012SC	(Trigger Sprayer)	67180-400-12	12 oz	12
4016C	(Dispensing Cap)	67180-400-16	15 oz	12

* 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.