



Microdox®

# Microdox® Bladder Rinse

Super-oxidized hypochlorous acid bladder rinse solution

Intended for use as an adjunct in the treatment and prevention of urinary tract infection

## CA - UTI | Infections


Urinary tract infection, the most common nosocomial infection worldwide, comprises 40% of all healthcare-associated infections & CAUTI represents 80% of this group.<sup>1</sup>

Catheter-associated urinary tract infections are a growing area of concern.

Antibiotic resistance continues to rise and the effect of traditional antimicrobials are further hindered by the persistence of biofilms

Healthcare associated UTIs cause 380,000 avoidable hospital bed days in Australia per year at a significant cost to both patients quality of life and the healthcare system as a whole.<sup>2</sup>

Without new technology to manage bioburden and subsequent urinary tract infections the future implications for contracting such an infection are significant



Resistance  
to all major UTI  
antibiotics significantly  
increased<sup>3</sup>  
(2009 - 2013)

*“The world is heading towards a post-antibiotic era, in which common infections and minor injuries, which have been treatable for decades, can once again kill.”<sup>4</sup>*

World Health Organisation 2014 AMR Report

## Why Microdox®

The use of hypochlorous acid derived solutions with proven antimicrobial efficacy have demonstrated effectiveness in resolving problematic CAUTI including multi-drug resistant infection with no promotion of bacterial resistance.<sup>7,9,10</sup> Microdox® is the most stable of these emerging technologies with proven antimicrobial and anti-biofilm efficacy at much lower concentrations<sup>7</sup>

Microdox is a class IIb Medical Device TGA registered as an electrolysed bladder rinse solution intended for use as an adjunct in the treatment and prevention of urinary tract infection. The device is intended for moistening of wounds, ulcers, cuts and abrasions during urological procedures. Sodium hypochlorite and hypochlorous acid are ancillary substances may have a local antimicrobial effect. Through reducing the microbial load and assisting in creating a moist environment, it enables the body to perform its own healing process. Microdox® can be broadly applied within a comprehensive procedure treatment. Do not use if sensitive to hypochlorous acid or sodium hypochlorite. ARTG: 273912

TeArai  
BioFarma 

Microdox® is an electrolysed solution that utilizes highly reactive, physiological concentrations of hypochlorous acid



Hypochlorous acid is naturally present in the body and is produced as a natural response to microbial invasion. The cells in our immune system, such as neutrophils produce this highly oxidizing molecule on demand through a mechanism known as a respiratory burst.

The low concentrations of highly reactive hypochlorous acid in Microdox® are potentially antimicrobial but uniquely, **non-cytotoxic** to human cells. Our natural antioxidant production protects our cells from this powerful oxidizing agent leaving only unicellular microbes susceptible to the induced osmotic rupture. <sup>5</sup>

Microdox® use has an exceptionally broad infection control spectrum including Bacteria (incl MDRO), Fungi, Viruses, Spores & Biofilms

“The ideal situation is a compound or a group of compounds that present not only antibiofilm activity but also the capacity to eradicate multidrug-resistant bacteria.”<sup>6</sup>

Microdox® Kill Time *in vitro* - 30 seconds

Organism	Log Reduction	Drug Resistant Organism	Log Reduction
E. coli	>5.5log	Staphylococcus aureus (MRSA)	>6log
Candida albicans	>6log	Vancomycin-resi enterococcus (VRE)	>6log
enterococci	>6log	Klebsiella oxytoca (MDR)	>6log
Pseudomonas aeruginosa	>5.5log	Enterococcus faecalis (VRE)	>6log
Klebsiella	>6log	Enterococcus faecium (VRE, MDR)	>6log
Enterobacter spp.	>6log	>6log = 99.999%	>5.5log = 99.99%

Electrolysed solutions are potentially effective at eradicating drug resistant pathogens and do not promote bacterial resistance<sup>7</sup>

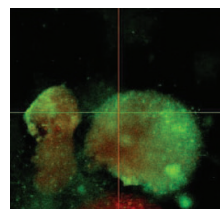
## Anti-Biofilm

Biofilm can be up to 1000-fold more resistant to antibiotics than planktonic cells<sup>6</sup>

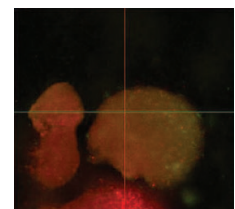
Microdox® has been clinically researched to physically reduce the biofilm matrix as well as to “rapidly penetrate biofilms killing microbes from within”<sup>7</sup>

Fluorescence microscopy of a mature, 6 day, *Pseudomonas aeruginosa* biofilm before and after 10 minutes of exposure to Microdox®

Green | Living Microbes Red | Dead Microbes



t=0



t=10

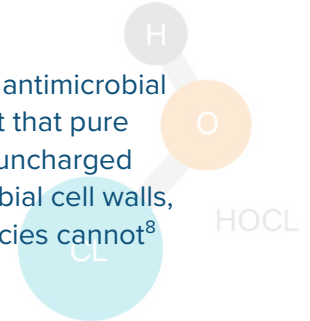
# Microdox® Tolerance

The use of a super oxidised solution is a growing concept in UTI management. Microdox® replicates a natural mechanism against pathogens: Foreign substances are removed and destroyed by a natural, non-antibiotic, physical process allowing Microdox® to remain non-cytotoxic and non-irritating.

## Comparative To Standard Antiseptic Solutions

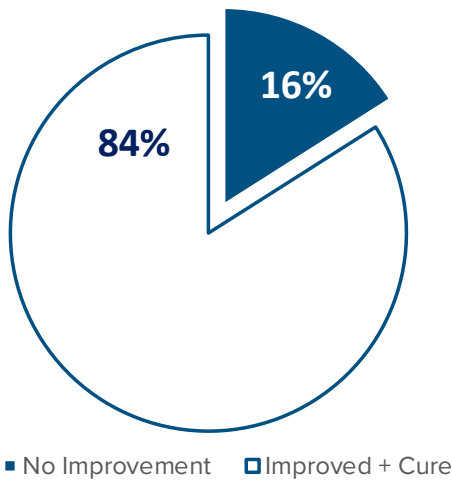
Test Agent	Toxicity Index <sup>8</sup>
Saline (0.9%)	1
<b>Microdox®</b>	10
Chlorhexidine (4% w/w)	10,000

The enormous difference in antimicrobial potency is due to the fact that pure hypochlorous acid as an uncharged species can penetrate microbial cell walls, whereas charged ionic species cannot<sup>8</sup>



## Evidence

\*The evidence below demonstrates efficacy of hypochlorous acid solutions in CAUTI management\*



### M Flemming et al 2011<sup>9</sup>

n=25 Hypochlorous acid solution 0.2%

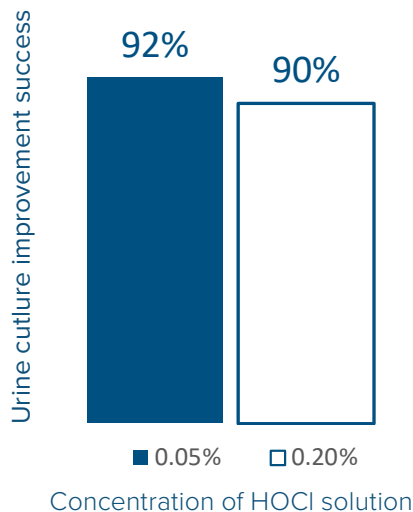
Baseline urine culture identified 33 organisms, including 13 multi drug resistant bacteria and 9 isolates of Candida sp. Success rate (cure + improved) was 84%.

The most frequently used regimen consisted of 2 bladder instillations via a urinary catheter every 12 hours. Mean duration of therapy was 2.62 days and number of treatments were 4.68.

### A Stock et al 2013<sup>10</sup>

n=100 Hypochlorous acid solution 0.05% Vs 0.2%

Success rate (cure + improvement of urine culture) 92% and 90% respectively + >95% response to drug-resistant microbes



Concentration of HOCl	0.05%	0.2%
Number of Treatments (mean)	5.04	5.44
Treatment days (mean)	2.68	2.86
Adverse events (total)	1	4
% MDRO Response	95%	100%
% Overall Response	92%	90%

References - 1: Watts et al 2016 Healthcare Infection Journal Preventing CAUTI., NSW ACI Project Report 2: Mitchell et al Journal of Hospital Infection 2016 Length of stay and mortality associated with health-care-associated urinary tract infections: a multi-state model 3: Fasugba et al PLOS 2016 Five-Year Antimicrobial Resistance Patterns of Urinary Escherichia coli at an Australian Tertiary Hospital: Time Series Analyses of Prevalence Data 4: World Health Organization 2014 Antimicrobial resistance global report 5: Thorn et al Eur J Clin Microbiol Infect Dis 2011, Electrochemically activated solutions: evidence for antimicrobial efficacy and applications in healthcare environments 6: Soto 2015 Advances in Biology, Importance of Biofilms in Urinary Tract Infections: New Therapeutic Approaches 7: Swanson et al IWII 2016 International Wound Infection Institute Guidelines 8: Rani et al 2014 Advances in Wound Care, The In Vitro Antimicrobial Activity of Cleansers at Nontoxic Concentrations 9: Flemming et al 2011 Sodium Oxychlorosene 0.2% Bladder Irrigation for Treatment of Patients with Urinary Tract Infections (UTIs) 10: Stock et al 2013 Determination of an optimal Oxychlorosene regimen for treatment of urinary tract infections

# Microdox® Use Guide

1. After decanting enough Microdox® for two repeated instillations into a sterile container, Using a sterile catheter syringe, draw up single dose of Microdox® (30ml\* )  
30ml is a guide, Instillation volumes may be directed by your healthcare professional and should ever exceed bladder capacity
2. Gently instil Microdox® through the catheter into a completely empty bladder  
This will require disconnection of the catheter to the leg bag. If you're unsure, ask your healthcare professional
3. By clamping or using catheter valve, close off outflow to ensure Microdox® remains in the bladder for 5 minutes  
Microdox must be emptied from the bladder within 15 minutes
4. Release the catheter clamp or open the catheter valve and drain the bladder completely
5. Repeat the process at least once more or until you achieve sediment free flow when emptying

Repeat

## Symptomatic UTI Treatment

Two (2) Sequential Rinses

Three (3) Consecutive Days  
Or Until Symptoms Resolve

## Prophylactic UTI Treatment

Two (2) Sequential Rinses

Once (1) or Twice (2)  
A Week As Required

If you have a spinal cord injury (SCI) or suffer from dysreflexia **only** use Microdox as directed by your healthcare professional  
Where possible mobilization of the body will aid in effectively dispersing Microdox throughout the bladder.  
Microdox® may be instilled up to 5 times every 12 hours during aggressive or MDRO infection management.

## Product Information

- Microdox® is presented as a 500ml screw cap bottle
- Microdox® is non-damaging to catheters or human tissue
- Microdox® has no special disposal requirements. Used or unused solution may be disposed of straight to the drain or toilet
- Microdox® may be used to cleanse the body and catheter pre-insertion to eliminate bacteria & ensure aseptic technique
- Microdox® is ready-to-use,
- Can be warmed before use (to 40°C)
- Microdox® is a Medsafe and TGA registered Medical Device
- Microdox® does not promote bacterial resistance<sup>7</sup>



- + Microdox® may be used in conjunction to antibiotics  
Microdox® should not be used with any treatment that alters urinary pH such as;  
Methenamine hippurate (Hiprex®) or Urinary Alkaliser (Ural®)



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### Product Description

Microdox® Electrolysed Bladder Rinse 500ml

### Internal Code

MDOX500 Box 24

### Microdox® Ingredients:

Super-Oxidised Water, Sodium Chloride (0.01%),  
Sodium Phosphate, Sodium Sulfate (1.082%), Ancillary substances  
including Hypochlorous Acid (0.009%), Oxygen and Ozone.