

**Application for Inclusion on
2017 WHO EML**

Electromicyn Solution and Hydrogel

(stabilised, pH neutral, super-oxidised hypochlorous acid)

Topical Antimicrobial Wound Healing Agent

1. Summary

Electromicyn is a class IIb medical device containing a stabilised, pH neutral, hypotonic solution of reactive oxidising species including hypochlorous acid, peroxide, ozone and superoxide. Electromicyn has demonstrated potent antimicrobial efficacy against a wide range of bacteria, viruses, fungi, moulds, spores, biofilms and simple eukaryotes. It exerts this potent antimicrobial effect by oxidative disruption of the outer membrane followed by rapid osmotic rupture and is therefore not susceptible to the development of microbial resistance.

Electromicyn is non-cytotoxic and instead has demonstrated significant wound healing capabilities through enhancement of fibrinocyte and keratinocyte migration, mast cell stabilisation and angiogenic reperfusion.

Electromicyn is non-toxic to humans and environmentally compatible.

Electromicyn has demonstrated superior wound healing versus a range of traditional antimicrobial agents including saline, povidone-iodine, chlorhexidine, benzoyl peroxide and systemic antibiotics across a range of wounds from peritonitis, diabetic foot ulcers and venous ulcers through to sinusitis, eczema and acne vulgaris.

Electromicyn has also demonstrated superior results as a medical disinfectant.

The cost per application of Electromicyn is significantly less than that of comparator antiseptic solutions and hydrogels. Furthermore, the duration of treatment with Electromicyn is significantly less than comparators making the cost per treatment even more affordable.

2. Name of the WHO technical department and focal point supporting the application.

Prof Benedetta Allegranzi, MD, DTM&H

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IPC team for the Ebola Response

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3. Supporting Organisations/Individuals

Electromicym is now included in the Antibiotic Guidelines 2015 edition for the Cook Islands and Western Samoa. The preparation of these guidelines is acknowledged as supported by the World Health Organisation (WHO).

Professor Bongiovanni concludes:

“Perhaps the greatest advance in VLU [venous leg ulcer] care is the addition of HCA [hypochlorous acid] to the treatment armamentarium. These aqueous solutions of hypochlorous acid, even in trace amounts, will kill most pathogens within 30 s of exposure. Additional actions of HCA include reduction of mast cell degranulation and active capillary dilation. The latter effect is of great importance in the diabetic VLU patient since one of the paradoxes in diabetes is the reduction of capillary perfusion via arteriovenous shunting at the microcirculatory level. The capillary dilation in turn elevates the tcpO₂ within the wound. We have observed that this improvement in periwound tissue oxygen concentration and perfusion can be persistent to 72h following exposure to the HCA.”¹

The 2016 International Wound Infection Institute (IWII) Consensus Guidelines published in the Journal Wound were supported by an educational grant from IWII and sponsored by a number of commercial organisational which did not include a manufacturer of NEW.² These consensus guidelines note that NEW (super-oxidised solution with hypochlorous acid) is the only wound care solution and hydrogel that penetrates biofilm and kills microbes from within while not promoting antimicrobial resistance.

Table 6: Cleansing solutions and gels				
Solution	Type	Cytotoxicity	Effect on biofilm	Comments
Sterile normal saline	Isotonic ¹⁰⁵	None	None	■ Sterile, non-antiseptic solution ¹⁰³
Sterile water	Hypotonic	None	None	■ Sterile, non-antiseptic solution ¹⁰³
Potable tap water	Varies in content	Unknown/variable	None	■ Not sterile ¹⁰³
Polyhexa-methylene biguanide (PHMB)	Surfactant antimicrobial	Low to none ²³	Surfactant qualities disrupt biofilm attachments ^{23, 106}	■ Available in gel and irrigation preparations that can be used together or separately ■ Lowers liquid surface tension, allowing greater spread and facilitating separation of non-viable tissue²³ ■ Does not promote bacterial resistance²³
Octenidine dihydrochloride (OCT)	Surfactant antimicrobial	■ <i>In vitro</i> tests show high toxicity¹⁰⁷ ■ Lack of absorption suggests no systemic effects¹⁰⁷ ■ Not shown to disrupt healing	■ Prevents formation of new biofilm for at least 3 hours¹⁰⁸ ■ Inhibits planktonic and bacterial biofilm growth for up to 72 hours¹⁰⁸	■ Available in gel and irrigation preparations that can be used together or separately¹⁰⁷ ■ Lowers liquid surface tension allowing greater spread and facilitating separation of non-viable tissue¹⁰⁸
Super-oxidised with hypochlorous acid (HOCL) and sodium hypochlorite (NaOCL)	Antiseptic	May vary depending on concentrations	■ Penetrates biofilm rapidly, killing formations from within¹⁰³ ■ Does not promote resistant bacteria strains¹⁰³	■ Purported to provide desloughing and antimicrobial activity ■ Available in gel and irrigation preparations that can be used together or separately
Povidone iodine	Antiseptic	Varies depending on concentrations ¹⁰⁸	■ Inhibits development of new biofilm¹¹⁰ ■ Eradicates young biofilm colonies¹¹⁰ ■ Significantly reduces mature biofilm colonies¹¹⁰	■ Modulates redox potentials and enhances angiogenesis, thereby promoting healing¹¹¹ ■ May inhibit excess protease levels in chronic wounds¹¹¹

Expert industry-sponsored recommendations on the use of super-oxidised hypochlorous acid, ³ were published in May 2015 by:

David G. Armstrong, DPM, MD, PhD

Gregory Bohn, MD, FACS, ABPM/UHM, FACHM

Paul Glat, MD, FACS

Steven J. Kavros, DPM, FACCWS, CWS

Robert Kirsner, MD, PhD

Robert Snyder, DPM, MSc, CWS

William Tettelbach, MD, FACP, CWS

Panel Recommendation 1: Cleanse the wound (if needed) with HOCl, followed by debridement, if needed. Follow a standard algorithm to prepare the wound bed, such as TIME.

Panel Recommendation 2: Treat infected wounds with HOCl by integrating into best practices according to wound etiology.

Panel Recommendation 3: For infected wounds, treat with HOCl for 15 minutes either intralesionally or by ensuring the wound is covered with the solution.

INDICATIONS FOR USE OF ECAS OF HOCL:

- **Diabetic Foot Ulcers**
- **Venous Leg Ulcers**
- **Pressure Ulcers**
- **Postsurgical wounds**
- **First-degree and second-degree burns**
- **Grafted and donor sites (not all solutions)**

4. International Non-proprietary Name (INN) and Anatomical Therapeutic Chemical (ATC) code of the medicine.

DO8AX07 sodium hypochlorite, hypochlorous acid as a pH-neutral electrolysed water (NEW).

5. Formulation and Strengths

Aqueous solution 30 ppm hypochlorous acid, 40 ppm sodium hypochlorite, sodium chloride plus other oxidative species.

Aqueous Hydrogel 80 ppm hypochlorous acid, 20 ppm sodium hypochlorite, sodium chloride, sodium magnesium fluorosilicate, sodium phosphate plus other oxidative species.

Freshly prepared Electromycin from the electrochemical anode contains the following approximate concentrations of oxidative species. ⁴

Oxidizing agent	Concentration (mg l ⁻¹)
Free chlorine	180
Total chlorine	180
Ozone	120
ClO ₂	5
H ₂ O ₂	Undetectable

6. Individual Medicine

Electromicyn is also available under the tradenames Microcyn, Dermacyn, MicroSafe, Microdacyn and Oxum in North America, Central America, South America, Middle East, India, Europe, Pacific Islands, and Asia. The tradename Electromycin (or NEW) will be used from here on throughout the application for clarity.

Electromicyn is classified by FDA, EMA and TGA as a Class IIb Medical Device, which are products that come into contact with injured skin and with an intended purpose of healing the breached dermis by ancillary effects.

7. Treatment Details

The solution is applied topically to disinfect, sterilise, irrigate, debride, and remove biofilms associated with wounds.

The Hydrogel is applied topically along with gauze or compression bandage for wounds that need to remain moist. Initially, in severe wounds the Hydrogel may need to be applied several times a day. Once healing is progressing, Hydrogel applications may only be necessary 2-3 times a week.

8. Public Health Relevance

Chronic wounds and the infections associated with them are responsible for a considerable increase in morbidity, mortality and cost of healthcare.

The use of biocides is an essential preventative control measure against the spread of nosocomial infections and multi-drug resistant bacteria within hospital and other healthcare and community settings. The general mechanism of action of biocides involves multiple target sites, compared to that of antibiotics which usually only have a single target site, making them highly efficacious as antimicrobials. This reduces the risk of developing resistance to these agents. Acquired resistance to antibiotics is of particular concern as the number of antibiotic prescriptions is increasing worldwide. Frequent use of several existing biocides, such as povidone-iodine, can cause respiratory or dermatological health problems in hospital workers.⁵ While repeated use of bleach in children has been reported to also cause respiratory and other infections.³⁷ Moreover, some biocides (e.g. acidic bleach) have the potential to cause corrosion or damage to equipment.⁵ Therefore, there is a need to explore alternative biocides, particularly since there is evidence for resistance to existing biocidal agents.⁶

Furthermore, Cochrane meta-analysis of some topical antimicrobial agents, such as silver sulphadiazine, has found “there is insufficient evidence to establish whether silver-containing dressings or topical agents promote wound healing or prevent wound infection.”⁷ A study of 0.3% triclosan in soap also reported that the *in vivo* antibacterial effect against 20 different bacterial strains was no better than soap alone.⁸

From out of this need for more effective, safe, and non-cytotoxic topical antimicrobial agents without the risk of antimicrobial resistance, a class of pH neutral electrolytically activated water solutions (NEW) have been developed. ⁹

NEW characteristically has an oxidation reduction potential (ORP) of +800 mV to +1,200 mV, creating an environment outside the working range of important microbial processes, including energy-generating mechanisms. ⁶ If immersed in these solutions, the microorganisms will be exposed to powerful oxidants which will sequester electrons with high efficiency from microbial structural compounds, and cause the rupturing of biochemical bonds and subsequent loss of function. Moreover, the high ORP environment is thought to create an unbalanced osmolarity between the ion concentrations in the solution and that within unicellular organisms, resulting in further damage to the membrane structures. This will cause increased membrane porosity. ¹ Thus, NEW mimics the body's natural cellular defence system in that the reactive oxygen species present mimic macrophage oxidative burst. ¹⁰

Following the disruption of the cellular membrane, the low osmolarity of NEW, typically around 13 mOsmol/L, causes cell death by osmotic rupture. ¹¹ Since the antimicrobial efficacy of NEW is essentially rapid osmotic shock, it is not believed to be susceptible to the development of antimicrobial resistance because of its extremely rapid physical mode of action and not cytotoxic mode of action. Furthermore, NEW has a broad biocidal effect against bacteria, viruses, fungi, spores, eukaryotes, and biofilms (Table 1).

Table 1: *In vitro* log kill per minute for NEW against various bacteria, viruses, fungi, spores, eukaryotes, and biofilms.

Target organism	Experimental kill rates (k) of various NEW (log ₁₀ CFU ml ⁻¹ reduction per minute) ^{9, 12, 13, 14, 15}
Aerobic/facultative bacteria	

<i>Acinetobacter spp.</i>	10.0
<i>Actinobacillus actinomycetemcomitans</i>	++
<i>Aeromonas liquefaciens</i>	13.8
<i>Alcaligenes faecalis</i>	13.6
<i>Bacillus subtilis</i>	1.7
<i>Bacillus cereus</i>	2.3-5.9
<i>Burkholderia cepacia</i>	34.5
<i>Citrobacter freundii</i>	13.3
<i>Campylobacter jejuni</i>	44.9
<i>Escherichia coli</i>	1.7-16.0
<i>Enterobacter aerogenes</i>	10.0
<i>Enterococcus spp.</i>	3.5-15.4
VRE	3.5-10.0
<i>Flavobacter spp.</i>	14.2
<i>Haemophilus influenzae</i>	>10.0
<i>Helicobacter pylori</i>	3.50
<i>Lactobacillus spp</i>	4.4-5.0
<i>Legionella pneumophila</i>	8.0
<i>Listeria monocytogenes</i>	1.3-16.3
<i>Klebsiella spp.</i>	10.0
<i>Micrococcus luteus</i>	10.0
<i>Mycobacterium spp.</i>	3.5-5.1
<i>Proteus spp.</i> 14.0 [54] 10.0 [52]	10.0
<i>Pseudomonas aeruginosa</i>	8.0-16.0
<i>Salmonella spp.</i>	5.2-16.0
<i>Serratia marcescens</i>	10.0
<i>Staphylococcus spp.</i>	3.9-16.0
MRSA	13.4
MRSE	3.2

<i>Stentotrophomonas maltophilia</i>	2.0
<i>Streptococcus spp.</i>	3.8-5.0
<i>Xanthomonas maltophilia</i>	++
Anaerobic bacteria	
<i>Actinomyces spp.</i>	2.9
<i>Bifidobacterium bifidum</i>	5.0
<i>Bacteroides fragilis</i>	10.0
<i>Clostridium difficile</i>	5.9
<i>Eubacterium lentum</i>	3.0
<i>Fusobacterium nucleatum</i>	2.9
<i>Peptococcus niger</i>	4.2
<i>Peptostreptococcus anaerobius</i>	4.1
<i>Prevotella melaninogenica</i>	5.8
<i>Porphyromonas spp.</i>	3.5
<i>Prevotella loeschii</i>	5.5
<i>Propionibacterium acnes</i>	4.6
<i>Veillonella parvula</i>	4.7
Viruses	
<i>FCV 2280</i>	4.0
<i>Flu A H1N1</i>	2.0
<i>Flu A H5N1</i>	6.0
<i>Flu A H9N2</i>	6.0
<i>Flu A H3N1</i>	2.0
<i>HIV 1</i>	8.0
<i>HSV 1</i>	2.0
<i>HSV 2</i>	3.0
<i>Norovirus</i>	3.0
<i>Polio 1</i>	6.0
<i>Rhino A1</i>	2.0

<i>RSV</i>	6.0
<i>WNV</i>	3.0
Bacterial Spores	
<i>Bacillus anthracis</i>	0.2
<i>Bacillus atrophaeus</i>	0.4-2.0
<i>Bacillus cereus</i>	1.32-6.98
<i>Bacillus subtilis</i>	1.0-15.0
<i>Clostridium difficile</i>	2.0
<i>Clostridium perfringens</i>	0.04
<i>Streptomyces spp.</i>	++
Bacterophages	
<i>Bacteriophage Qβ</i>	++
Eukaryotes	
<i>Aspergillus spp.</i>	5.25
<i>Candida spp.</i>	3.5-16.0
<i>Cryptosporidium parvum</i> oocysts	++
<i>Various environmental fungi</i>	++
Biofilms 24h	
<i>Staphylococcus aureus</i>	6.0
<i>Pseudomonas aeruginosa</i>	6.0
<i>Candida albicans</i>	6.0

Electromycin has been studied *in vitro* against a series of bacteria resistant to household bleach (40% sodium hypochlorite at 24,000 ppm free chlorine). ¹⁶ At 30s of Electromycin, 3 out of 9 isolates demonstrated a 5 log kill, while after 1 min exposure, 4 out of 10 isolates had a 5 log kill and the remaining 6 isolates a 4 log kill. After 2 min exposure to Electromycin there was no detectable bacteria in any of the 10 isolates. In contrast, after 30 s exposure to household bleach, no isolates demonstrated any detectable

reduction in bacterial counts. While after 2 min exposure to household bleach 5 out of 9 isolates demonstrated no detectable kill, 1 isolate a 4 log kill, 2 isolates a 5 log kill and 1 isolate a 6 log kill.

NEW is not merely an effective biocidal agent. It has been shown to have potent wound healing effects through significantly increasing the skin fibroblast cell migration. In vitro a single wound was created across a keratinocyte monolayer which was then incubated with either NEW or povidone-iodine. Keratinocyte migration at 24 hours was approximately +25% versus baseline ($p < 0.05$) with NEW compared to approximately -20% at 24 hours versus baseline for povidone-iodine ($p < 0.05$).¹² Povidone-iodine demonstrated cytotoxic activity, while NEW demonstrated wound healing efficacy.

The measurement of metabolic activity (MTT assay) is a reliable measurement of cytotoxicity to the basal layer (BL) as it measures metabolic activity only in undifferentiated keratinocytes in the BL, in the first suprabasal layer of the epidermis, and in the fibroblasts in the dermis. A study comparing the cytotoxic effect of a range of antiseptics on skin autografts using MTT found that NEW had approximately 85% MTT of controls whereas Betadine had 0%.¹⁷

NEW has been demonstrated to significantly improve wound reperfusion. Documented improvements in TcPO₂ are all measured within 1 cm of the ulcer and are sustained for at least 36 hours without additional exposure to superoxidized water.¹⁸

Mast cell degranulation initiates the early phase of allergic responses. Pre-treatment of mast cells with 25% and 50% NEW inhibited antigen-induced mast cell degranulation by 75–80%.¹⁹

9. Review of Evidence: Comparative Efficacy

Overview

Condition	Design	Comparator	N	Outcome for Microdacyn group	Stats <i>p</i>	Reference
Chronic & acute wounds	RCT	Povidone-iodine	200	Day 21 wound reduction (70% vs 50%), ↓ pus discharge and time to granulation	na	Kapur 2011 ²⁰
DFU	Non-R	Povidone-iodine	218	Faster healing, ↑ % successfully treated (odds ratio 3.4 ± 1.7-7.0)	< 0.005	Dalla Paola 2006 ²¹
DFU	RCT	Saline	100	↓ 1-7 days in hospital (68% vs	<0.05	Hadi 2007 ²²

				20%), ↑ DFU score reduction IV to I (62% vs 15%)		
Burns (BICU)	Non-R	Mupirocin, chlorhexidine	na	↓ global MRSA infection (incidence rate ratio 0.328, 95% CI 0.167-0.646)	0.001	Gray 2016 ²³
Chronic wounds	RCT	Povidone-iodine	40	Days to ↓ signs of infection (7.9, 95% CI 6-15 vs 5.4, 95% CI 3-9), ↓ days in hospital (12.3, 95% CI 8-19 vs 8.2, 95% CI 7-10)	na	Ricci 2007 ²⁴
DFU	RCT	Povidone-iodine	45	↓Periwound cellulitis (56% vs 19%, ARR 37%, 95% CI 7.61-66.75) ↓odour (ARR 75%,	<0.05	Martinez-De Jesus 2007 ¹⁰

				95% CI 53.75-96.22)		
Peritonitis	RCT	Saline lavage	80	↓purulent discharge (52.5% vs 20.0%), ↓burst abdomen (47.5% vs 27.5%)	<0.01	Khan 2009 ²⁵
Diabetic ulcers	RCT	Saline	100	↑ Healing (40% vs 78%), ↓ bacteria (32% vs 76%)	<0.01	Suri 2008 ²⁶
Venous leg ulcers	Non-R, cohort	-	897	100% healed, ↑periwound tissue oxygen concentration T _{cp} O ₂ (NIDDM baseline 111 ± 11 vs 179 ± 14 at 30s vs 146 ± 25 at 72h)	na	Bongiovanni 2016 ²⁷
Post-op	Non-R	Povidone-	40	Faster healing	0.00361	Piaggese 2010 ²⁸

DFU		iodine		(212.3, 95% CI 178.6-246.9 vs 144.6, 95% CI 125.4-163.6), ↓ antibiotics, ↓ re-operation		
Sternotomy wounds	RCT	Povidone-iodine	178	↓ infections (15.6% vs 5.7%)	0.033	Mohd 2010 ²⁹
Post-op wounds	RCT	Povidone-iodine	100	Faster healing, ↓ infections (36% vs 15%)	< 0.0005	Pandey 2011 ³⁰
Mild DFU	RCT	Levofloxacin + saline irrigation	67	↑ Healing (56.3% vs 93.3%, OR 2.8, 95% CI 0.7-10.7)	0.033	Landsman 2011 ³¹
Acute peritonitis	RCT	1 hour saline lavage	100	↓ surgical site infections (40% vs 14%)	0.0034	Garg 2013 ³²
Infected traumatic	RCT	Povidone-iodine	60	Fewer symptoms and signs of	< 0.004	Mekkawy 2014 ³³

wounds				infection (no serous discharge 10% vs 100%)		
DFU	RCT	Povidone-iodine	60	↑ Mean % reduction in ulcer area (40.90 ± 8.76 vs 58.90 ± 5.21)	0.024	Prabhaker 2016 ³⁴
IPD	RCT	Povidone-iodine	111	↓ infections (24.5% vs 6%), faster healing	<0.05	Méndez-Durán 2013 ³⁵

DFU – Diabetic Foot Ulcer

IPD – Intraperitoneal Dialysis

RDT – Randomised controlled trial

Non-R – Non-randomised trial

BICU – Burns Intensive Care Unit

Stats - Statistics

MRSA – Multi-drug resistant *S aureus*

na – not available

ARR – Adjusted Risk Ratio

NIDDM – Non-Insulin Dependent Diabetes Mellitus

s – seconds

h - hours

Kapur V and Mawaha A K. Evaluation of effect and comparison of superoxidised solution (Oxum) v/s povidone iodine (Betadine). *Ind J Surg.* 2011; 73(1); 48-53. ²⁰

Objective: To evaluate the effect of Electromycin V/s povidone iodine (Betadine) on similar types of wounds.

Design: 200 patients having wounds (acute and chronic ulcers, diabetic foot ulcers, venous stasis ulcers, cellulitis, carbuncles, abscesses of different types, Burns, traumatic wounds, post-surgical wounds, pressure/bed sores, fistula in ano, gangrenous wounds and internal irrigation like peritoneal lavage in peritonitis) prospectively randomized to treatment with either NEW-saturated gauzes or povidone iodine-saturated gauzes. All patients received antibiotics.

Results: The mean follow-up of 21 days showed that the average reduction in Diabetic Foot Ulcer (DFU) wound size in the Electromycin-treated group was 70% compared to 50% in the povidone iodine-treated group. Pus discharge in patients with abscesses was reduced earlier in the Electromycin-treated group (100% vs. 90% at day 12 for Electromycin vs. povidone-iodine) and there was an earlier appearance of granulation and epithelisation (100% versus 85% at day 18 for Electromycin versus povidone-iodine). Electromycin was safe and efficient as a wound care product and superior to povidone-iodine.

Dalla Paola L et al. Use of Dermacyn, new antiseptic agent, for the local treatment of diabetic foot ulcers. *J Wound Heal.* 2005; 2; 201. ²¹

Objective: To evaluate the efficacy of a novel product NEW compared with standard treatment (10% povidone-iodine) in the treatment of diabetic foot ulcers.

Design: An open-label, non-randomised trial involving two hundred and twenty consecutive patients with stage II/III infected diabetic foot ulcers (DFU) treated with either Electromycin dressings or povidone-iodine dressings for 10 days plus oral or parenteral antibiotics as necessary. The mean follow-up time was 94.8 days.

Results: At the time of surgical closure, 75% of the Electromycin group and 48% of the povidone-iodine group were microbiologically negative ($p<0.005$).

Hadi S F et al. treating infected diabetic wounds with superoxidized water as anti-septic agent: a preliminary experience. *JCPSP*. 2007; 17(12); 740-743. ²²

Objective: To evaluate the effectiveness of Electromycin in diabetic patients with different wounds.

Design: One hundred patients with DFU wounds randomised to treatment with either daily NEW or saline soaked gauzes. All patients received IV antibiotic therapy and surgical debridement as necessary.

Results: Patients treated with NEW had a significantly shorter period of hospitalisation than saline-treated patients (1-7 days hospitalisation of 68% vs. 20%, $p<0.05$) and a higher proportion experienced a down-grading of their DFU (IV to I, 62% versus 15%, $p<0.05$).

Gray D et al., Universal decolonization with hypochlorous solution in a burn intensive care unit in a tertiary care community hospital. *Am J Infect Cont*. 2016: doi.org/10.1016/j.ajic.2016.02.008. ²³

Objective: To evaluate the efficacy of universal decolonization to decrease health care–associated infections caused by MRSA in patients admitted to a burn intensive care unit (BICU) using mupirocin and NEW for skin decolonization.

Design: A retrospective, single institution cohort study.

Results: Global MRSA infection rates per 1,000 patient days were 7.23 pre-intervention and 2.37 post-intervention, resulting in an incidence rate ratio of 0.328, favoring post-intervention (95% confidence interval, 0.167-0.646; $P = .001$). BICU patients without

universal decolonization had 3.05 times higher risk of acquiring an MRSA infection than those with universal decolonization. No complications were noted from use of hypochlorous acid solution for skin decolonization.

Ricci E et al., Clinical results about an antimicrobial solution (Dermacyn® Wound Care) in the treatment of infected chronic wounds. Poster presented at: 17th Conference of the European Wound Management Association (EWMA); 2007 May 2-4; Glasgow, UK. ²⁴

Objective: To evaluate the clinical performance of the antiseptic solution Electromicyn.

Design: Forty patients with infected wounds were randomly assigned twice daily dressings of either Electromicyn or povidone-iodine. All patients received standard antibiotic therapy.

Results: The Electromicyn group had fewer days on average with clinical signs of infection (7.9 vs 5.4), odour (19 vs 2) and hospitalised (12.3 vs 8.2).

Martinez-de Jesus F et al. Efficacy and safety of neutral pH superoxidised solution in severe diabetic foot infections. *Int Wound J*. 2007: doi:10.1111/j.1742-481X.2007.00363.x ¹⁰

Objective: To assess the efficacy of Electromicyn for infection control, odour reduction and surrounding skin and tissue damage on infected diabetic foot ulcerations.

Design: A randomised, single-blind trial of forty-five patients with DFU treated with standard care with or without Electromicyn, which was applied as a foot soak followed by spray application. Standard care consisted of broad spectrum IV antibiotics, surgical debridement, and glycaemic control.

Results: Odour reduction was achieved in all NEW-treated patients compared to patients treated without NEW (100% versus 25%; $p<0.01$) and surrounding cellulitis diminished in 17 patients (80.9% versus 43.7%; $p<0.001$). Nineteen patients in the NEW group

showed advancement to granulating tissue stage (90.4% versus 62.5%; $p<0.05$) with significantly less tissue toxicity (94% versus 31.2%; $p<0.01$).

Khan S M et al. Evaluation of pre-operative peritoneal lavage by super-oxidized solution in peritonitis. *Mid East J Int Med*. 2009; 2(3); 15-35. ²⁵

Objective: To assess the role of intraperitoneal lavage with NEW in patients peritonitis.

Design: Eighty patients with peritonitis were randomly assigned to either 1 hour gastric lavage with saline or NEW following surgery.

Results: Purulent discharge occurred in 20% of patients receiving NEW lavage versus 52.5% of patients receiving saline lavage ($p<0.01$). The incidence of burst abdomen among the NEW lavage patients was significantly less than those receiving saline lavage (27.5% versus 47.5%, $p<0.05$).

Suri A P S. The effectiveness of stable pH-neutral super-oxidized solution for the treatment of diabetic foot wounds. Poster at Diabetic Foot Global Conference, Los Angeles, 2008. ²⁶

Objective: To evaluate the clinical efficacy and microbial load reduction of Electromicyn compared with saline in patients with diabetic foot wounds.

Design: A randomised trial of 100 patients with diabetic foot ulcers 2-15 cm in diameter treated with a once daily bath of either Electromicyn or saline for 16 weeks.

Results: The higher proportion of the Electromicyn treated group had a significant reduction in bioburden (76% vs 32%) and healed wounds (78% vs 40%).

Bongiovanni C M. Effects of hypochlorous acid solutions on venous leg ulcers (VLU): experience with 1249 VLUs in 897 patients. *J Am Coll Clin Wound Spec.* 2016; 10.1016/j.jccw.2016.01.001 ²⁷

Objective: To assess the impact of comorbidities and identify factors that accelerate the healing rate of venous leg ulcers.

Design: An extensive, retrospective analysis of our experience in a diverse population.

Results: Initial treatment of all venous leg ulcers involved cleaning and debriding foreign matter, debris, and necrotic material via application of copious NEW, and under pressure if necessary. Where needed, this was accompanied by abrasion using sterile gauze soaked with NEW. In all cases requiring sharp debridement, this was performed in an appropriate surgical facility and within 10 days of presentation. Following initial treatment, all ulcers were dressed and/or loosely packed with sterile gauze soaked with NEW. An appropriately compressive, multi-layered, overlying bandage system, utilizing short-stretch or non-stretch materials was constructed such that the greatest compression was at the ankle level. Light abrasion utilizing sterile cotton gauze soaked with NEW, followed immediately by flushing the wound with more of the solution effectively destroyed the extant biofilm *in situ*. With several repetitions over several days, it also prevented biofilm from re-establishing. All 1249 venous leg ulcers reported in this data set were healed completely. The longest healing times were encountered by 10 patients for whom compression therapy was contraindicated: diabetic patients with severe arterial occlusive disease [ABI < 0.6]. Nonetheless, aggressive management with NEW resulted in complete wound closure within 180 days for this treatment refractory cohort. Perhaps the greatest advance in Venous Leg Ulcer (VLU) care is the addition of NEW to the treatment armamentarium.

Piaggessi A et al. A randomised controlled trial to examine the efficacy and safety of a new super-oxidized solution for the management of wide postsurgical lesions of the diabetic foot. *Int J Low Extrem Wounds.* 2010; 9(1); 10-15. ²⁸

Objective: A study of the safety and efficacy of NEW compared with standard treatment in the management of wide post drainage lesions of the infected diabetic foot ulcers.

Design: Non-randomised cohort study involving forty patients with >5 cm² postsurgical wounds secondary to infected DFU treated with either Electromycin or povidone-iodine as adjuncts to systemic antibiotics and debridement as needed. Patients were followed for 6 months.

Results: Healing as measured by complete re-epithelisation at 6 months occurred in 90% of the Electromycin -treated group compared with 55% of the povidone-iodine-treated group ($p<0.01$). The Electromycin -treated group also experienced significantly shorter period of antibiotic treatment (10.1 weeks vs. 15.8 ($p = 0.016$) and interventions (4 vs. 11, $p=0.022$). The Electromycin -treated group also had fewer episodes of reinfection ($p<0.01$).

Mohd A R R. Dermacyn® Irrigation in Reducing Infection of a Median Sternotomy Wound. *Heart Surg Forum*. 2010; 13(4); 228-232. ²⁹

Objective: To compare the effectiveness of Dermacyn irrigation and povidone-iodine with respect to reducing the incidence of sternotomy wound infection following CABG.

Design: A prospective randomised trial of 178 post-CABG patients who were treated with either NEW or povidone-iodine wound irrigation.

Results: The incidence of sternotomy wound infection was five (5.7%) of these cases were from the Electromycin group, and 14 (15.6%) were from the povidone-iodine group ($P = 0.033$). No Electromycin-related complication was identified.

Pandey P K et al. Outcomes of superoxide solution dressings in surgical wounds: a randomized case control trial. *Int J Biol Med Res*. 2011; 2(4); 965-968. ³⁰

Objective: To evaluate the role of NEW in wound healing. At the same time an effort was made to compare the efficacy and outcomes of NEW dressings and those with povidone iodine solution.

Design: Randomised controlled trial of one hundred patients with a variety of wounds treatment with either Electromycin-saturated dressings (Group A) or povidone-iodine saturated dressings (Group B).

Results: The incidence of infection in primarily sterile cases was 15% in group A and 36% in group B, respectively. The most common infecting organism isolated in the study was *Pseudomonas aeruginosa* followed by *Staphylococcus aureus* and *Klebsiella* spp. Decrease in surface area of wounds at the end of the 1st, 2nd, 3rd, and 4th weeks, which was statistically significant, was more in the Electromycin group compared to the povidone-iodine group ($p=0.005$, 0.002 , <0.001 , and 0.001 , respectively). This study revealed less induration in wound margins when NEW was used. This finding appears to be consistent with the fact that this solution does not damage cellular elements or restrict microcirculation of wound.^{23, 24} Thus, the solution ensures the wellbeing of surrounding healthy tissues. In addition, this study also revealed the early reduction in discharge from wounds dressed with Electromycin as compared to povidone-iodine solution. Granulation tissue formation was earlier in the Electromycin group as compared to the povidone-iodine group and also covered a greater wound surface area as compared to povidone-iodine.

Landsman A et al. An open-label, three-arm pilot study of the safety and efficacy of topical Microcyn Rx wound care versus oral levofloxacin versus combined therapy for mild diabetic foot infections. *J Am Podiatr Med Assoc.* 2011; 101(6); 484-496.³¹

Objective: To test whether a topical Electromycin is a safe and effective treatment for mildly infected diabetic foot ulcers.

Design: Sixty-seven patients with mildly-infected DFU were randomised to 10 days therapy with either daily Electromycin treatment irrigation alone, daily saline irrigation plus levofloxacin, or daily Electromycin treatment irrigation plus oral levofloxacin.

Results: The intention-to-treat clinical success rate at day 10 was higher in the Electromycin -treated alone group (75.0%) than in the saline plus levofloxacin group (57.1%) or in the Electromycin treatment plus levofloxacin group (64.0%). In the intention-to-treat group, the overall clinical success rate (cure or improvement) was highest in the Electromycin alone group at visits 3 and 4. In the intention-to-treat sample at visit 3, the clinical success rate, defined as patients achieving cure or improvement, was higher in the Electromycin alone group (75.0%) than in the saline plus levofloxacin group (57.1%) or in the Electromycin plus levofloxacin group (64.0%). Results at visit 4 were similar: 75.0% for the Electromycin alone group, 52.4% for the saline plus levofloxacin group, and 72.0% for the Electromycin plus levofloxacin group. The differences in clinical success rates among the three treatment groups were not statistically significant, however Electromycin alone seemed to have an effect on clinical success that was comparable with that of saline plus levofloxacin. The per-protocol test of cure for patients treated with Electromycin alone was 93.3% vs. 56.3% for saline plus levofloxacin ($p=0.033$).

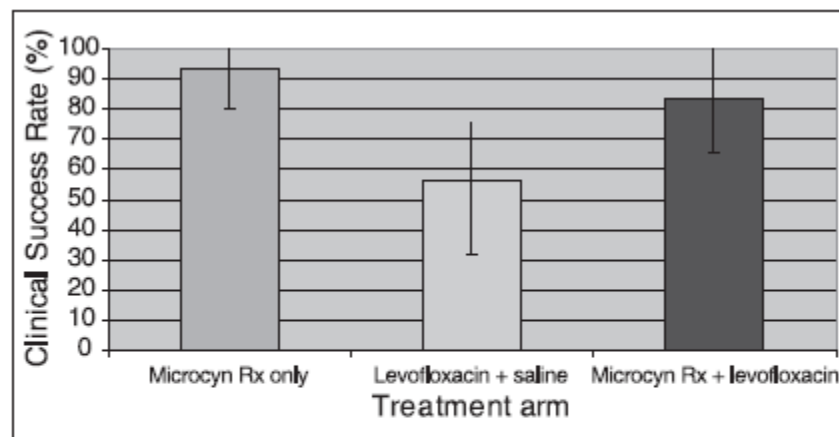


Figure 3. Relative clinical success rates by treatment arm. Error bars represent 95% confidence intervals.

Garg P K et al. Evaluation of intraoperative peritoneal lavage with super-oxidized solution and normal saline in acute peritonitis. *Arch Int Surg*. 2013; 3(1); 43-48. ³²

Objective: To evaluate the role of intraperitoneal lavage with normal saline and normal saline followed by NEW in patients with acute peritonitis.

Design: One hundred patients were randomly allotted by slip method into two groups of 50 each. In the control group, after the definitive surgery for the pathology of peritonitis, the peritoneal cavity was lavaged with normal saline and closed after putting in drains. In the study group, after the definitive surgery the peritoneal cavity was lavaged with saline followed by 100 ml of NEW and drains were closed for 1 h after abdominal closure. The patients were followed-up for morbidity and mortality.

Results: Surgical site infection occurred in 14% of NEW lavage patients vs. 40% of saline lavage patients ($p=0.0034$). Eight (16%) patients in the control group (saline lavage) compared to 2 (4%) patients in the study group (NEW lavage) died in the study.

Mekkawy M M and Kamal A. A Randomized Clinical Trial: The Efficacy of Hypochlorous Acid on Septic Traumatic Wound. *J Ed Prac*. 2014; 5(16); 89-100. ³³

Objective: To evaluate the efficacy of Electromicyn as a wound care agent in a septic traumatic wound.

Design: A randomized clinical trial of sixty patients with septic trauma wounds at a single centre to treatment with either daily Electromicyn washes or daily povidone-iodine (P-I) washes.

Results: Wound pain (no pain at day 14, 100% Electromicyn versus 16.6% P-I, $p=0.004$), odour (no odour at day 14, 100% Electromicyn versus 13.3% P-I, $p=0.001$), no discharge (serous at day 14, 100% Electromicyn versus 10% P-I, $p=0.004$) and bacterial count (reduction in day 14 quantitative count, $p=0.0001$) were dramatically reduced by using as Electromicyn compared to

povidone-iodine. At day 14, 90% of the Electromicyn treated group had wounds ready for surgical reconstruction compared with 0% for the P-I group.

Electromicyn was an effective, easy to perform, comfortable, inexpensive and safe in treatment for infected acute traumatic wounds and allows for earlier surgical closure and hospital discharge. Electromicyn controls the tissue bacterial bioburden without inhibiting the wound healing process rapidly relieving pain with the area becoming well-prepared for skin flap or graft.

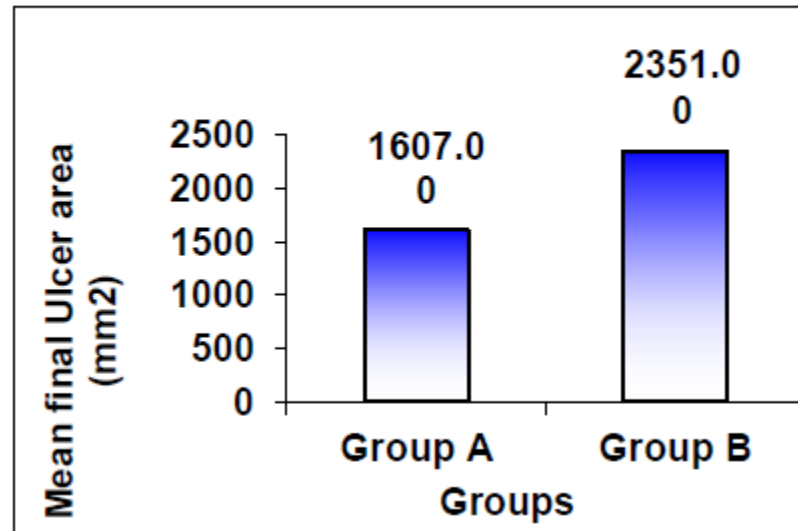
Prabhakar K B S et al., Comparison of Super-oxidized Solution versus Povidone Iodine in Management of Infected Diabetic Ulcers: Our Experience. *Int Arch Integ Med.* 2016; 3(5); 151-158. ³⁴

Objective: To compare the efficacy of dressings with Electromicyn versus povidone iodine in the management of infected diabetic ulcers.

Design: This one year randomized controlled trial was conducted on a total of 60 patients presenting with infected diabetic ulcers. Patients were divided into two groups of 30 each based on computer generated randomization that is, group A (Electromicyn dressing) and group B (Topical povidone iodine dressing). Wound was observed for decrease in size of the ulcer, granulation, tissue quality and discharge from the wound at the end of each week for two weeks.

Results: The mean percentage reduction in ulcer area among patients with group A was significantly high (58.90 ± 5.21 percent vs. 40.90 ± 8.76 percent; $p=0.024$).

Graph - 2: Comparison of final ulcer area.



Méndez-Durán A. Efficacy and safety of the use of superoxidized solution in the prevention of dialysis-related infections. *Dial Transpl.* 2013; 34(4); 160-165. ³⁵

Objective: To evaluate the efficacy and safety of Electromicyn in reducing the frequency of dialysis-associated infections.

Design: Randomised controlled trial in one hundred and eleven intraperitoneal dialysis patients treated with either povidone-iodine or Electromicyn following catheter placement.

Results: After 8 weeks follow-up 24.5% of the povidone-iodine group had experienced catheter-related infections compared with 6% in the Electromicyn group ($p < 0.05$). The mean time resolution of infection in the povidone-iodine group was 12 days compared with 4 days for the Electromicyn group ($p < 0.05$).

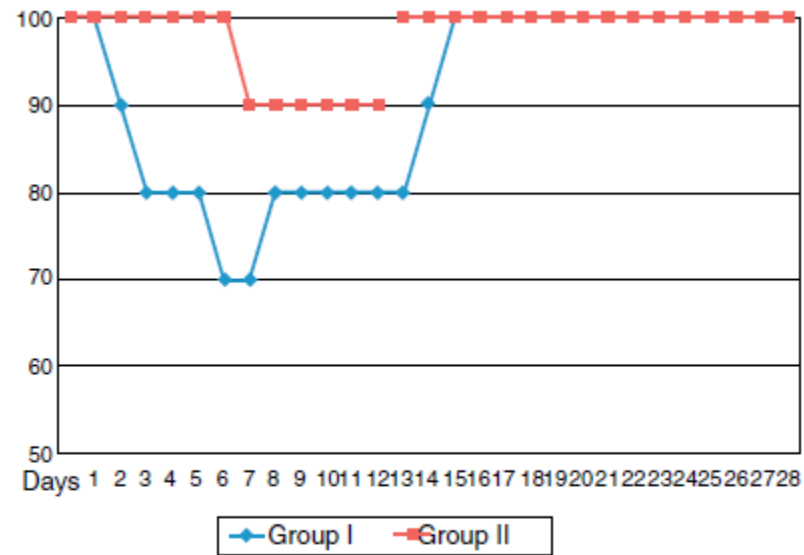


Figure 2 Exit site. Resolution time of infection. $p < 0,05$; RR: 20% In first 7 days.

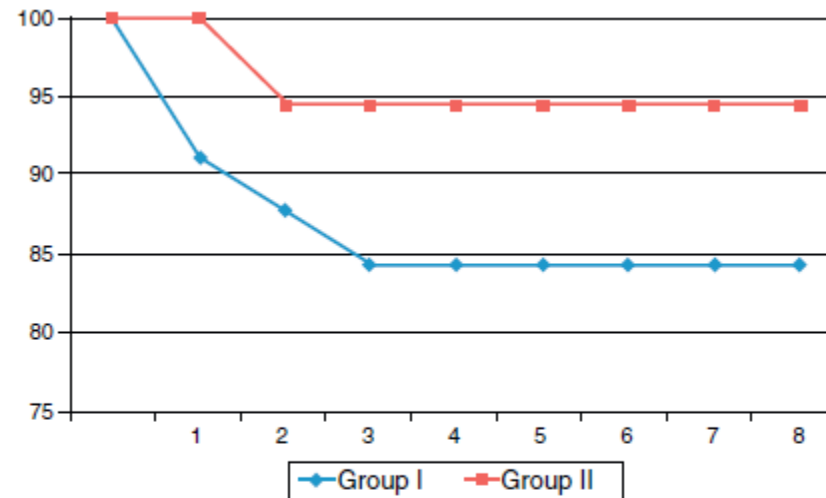


Figure 4 Exit-site. Resolution time of the serous exudate.
 $p < 0,05$; RR: 12,2%.

10. Summary of Safety Evidence

Microdacyn mimics the body's natural cellular defence system in that the Reactive Oxygen Species (ROS) mimic macrophage oxidative burst. ¹⁰ The extreme hypotonicity leads to osmotic shock and microbial rupture. ⁶

The goal of antiseptic is to reduce potentially pathogenic microbial populations to safe levels. In the clinical environment, agents must not be hazardous or toxic to living tissue according to their particular application and in-use concentrations. A large scientific body of evidence now exists indicating the safety and non-toxicity of NEW. NEW does not target cell nuclei, produces only limited damage to cell membranes, and does not induce DNA oxidation or accelerated ageing. It is also worth noting that NEW presents no environmental hazard since it slowly reverts to salt water during the period of chemical relaxation and is effectively inactivated by organic matter when present in trace amounts. ⁶

A single-dose and 28-day repeated dose oral toxicity study of NEW in rats found no evidence of adverse effects. In addition, mice given free access to NEW as drinking water for 8 weeks showed no toxic side effects. ³² Moreover, no toxicity was observed using in-use concentrations during acute oral toxicity tests (LD₅₀) upon application to mucous membranes, in accumulation irritation tests, or in sensitisation tests, indicating its biocompatibility. ³⁶ In fact, the observed biocompatibility of NEW has often been determined at relatively high exposure levels, in comparison with the anticipated low levels that would be used in real clinical situations. The incubation of NEW with human cell lines *in vitro* has shown more mixed results where some studies had no effect, while others had significant cytotoxicity, although usually to a lesser degree than other commonly used biocides. However, *in vitro* cytotoxicity is not always indicative of toxicity when used *in vivo*, as observed previously. *In vitro* mutagenicity studies failed to find any evidence of NEW induced genotoxicity, using either the Ames test or the genotoxicity micronucleus test, indicating its safe usage. ^{36, 37} Moreover, a recent wide-ranging toxicity study on a neutralised NEW found that it did not degrade nucleic acids or induce oxidative damage in dermal fibroblasts *in vitro*. ¹⁰ This study led the authors to conclude that NEW did not target cell nuclei, produced only limited damage to cell membranes and did not induce DNA oxidation or accelerated ageing. It is also worth noting that NEW presents no environmental hazard because it slowly reverts to salt water during the period of chemical relaxation, and is effectively inactivated by organic matter when present in trace amounts. ⁹

Electromicyn technology is a pH neutral, hypotonic solution of highly oxidative species including hypochlorous acid, ozone, superoxide, and peroxide. It exerts powerful antibacterial, antiviral, antifungal, sporicidal, and antibiofilm activity based principally on a physicochemical mode of action, thereby avoiding the risk of resistance developing. Electromicyn is not only potently biocidal but also has significant wound healing properties, which is unique amongst other topical antiseptics. In clinical trials, Electromicyn demonstrated generally superior wound healing and antiseptic outcomes vs. commonly used alternatives that are currently included on the WHO EML. The acute and chronic safety of Electromicyn is well documented such that it has FDA approval for use around eyes and on mucosa. Furthermore, Electromicyn is offered at a lower cost than the alternative topical antiseptics listed in the WHO EML.

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11. Comparative Cost

Pricing for 500 mL 10% povidone-iodine to Fiji in 2006 was 6.68 USD or 0.134 USD per 10 mL. The current price for 500 mL 10% povidone-iodine with 30% ethanol in New Zealand is USD 7.13 or USD 0.143 per 10 mL. The current pricing of 100 mL 10% povidone-iodine in Australia is USD 9.46 or USD 0.946 per 10 mL.

The proposed pricing of Electromicyn Wound Care Solution 500 mL (NEW supplied by Te Arai BioFarma Ltd) spray bottle is 5.52 USD or 0.11 USD per 10 mL.

The proposed pricing for Electromicyn Hydrogel 250 g spray bottle is 6.00 USD or 0.24 USD per 10 mL.

The cost per application of Electromicyn is significantly less than that of comparator antiseptic solutions and hydrogels. Furthermore, the duration of treatment with Electromicyn is significantly less than comparators making the cost per treatment even more affordable.

	Electromicyn Solution 10mL	Povidone- iodine Fiji 2006 10mL	Povidone- iodine New Zealand 10mL	Povidone- iodine Australia 10mL	Electromicyn Hydrogel 10mL	Solosite Hydrogel New Zealand 10mL	Intrasite Gel New Zealand 10mL
Price USD	0.110	0.134	0.143	0.946	0.240	1.927	4.52