PRONTOSAN® made easy

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Introduction

This made easy section describes the mode of action, supporting evidence and practical application of the Prontosan® (B. Braun) range of wound cleansing agents. Regular cleansing and debridement are basic principles of wound bed preparation (WBP) and modern wound management[1-3]. These actions can address the barriers to healing by removing devitalised tissue, re-balancing the bioburden and reducing exudate to help prepare the wound bed for closure. The removal of biofilms and preventing their regrowth is commensurate with effective wound bed preparation[4,5].

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What is Prontosan® Wound Irrigation Solution and Gel?

Prontosan® Wound Irrigation Solution, Prontosan® Wound Gel and Prontosan® Wound Gel X are wound cleansers made from purified water and two key ingredients:

- **Polyhexamethylene biguanide (PHMB), an antimicrobial agent (0.1%)**
- **Betaine, a surfactant (0.1%)** (Box 1).

These products can be used for cleansing, rehydrating and decontaminating acute and chronic wounds that are at risk of infection by aiding the removal of bacteria and debris, and disrupting biofilm. The irrigation solution can be used to rinse the wound prior to application of the gel, which is available in two preparations. Prontosan® Wound Gel can be used on small wounds, cavities and other difficult to reach areas. Prontosan® Wound Gel X is highly viscous and can be used when larger quantities are required.

The role of wound cleansing in WBP

WBP has gained international recognition as a measured approach to accelerate wound healing, or to facilitate the effectiveness of other therapeutic measures[1-3].

Bacterial contamination of both acute and chronic wounds will inevitably occur to some extent due to the loss of skin barrier function[6], especially if this is prolonged and associated with underlying pathology or decreased host resistance[7]. This may also put the patient at risk of potentially life-threatening sepsis[8]. Maintaining the wound bioburden at a level the host can control is therefore vital in preventing the onset of infection and associated increased patient morbidity[9].

Box 1 What are surfactants?

Surfactants lower the surface tension of the medium in which they are dissolved, making it easier to lift off dirt and debris and suspend it in solution so that it does not recontaminate the wound.

The presence of biofilms in chronic wounds as a cause of delayed healing has recently gained acceptance [4,10,11]. Biofilms are complex microbial communities living within a three-dimensional extracellular polysaccaride (EPS) matrix embedded in a thick slimy blanket of sugars and proteins. The matrix acts as a barrier, protecting the micro-organisms from cellular and chemical attack[12].

Biofilms are not visible to the naked eye and cannot be detected by routine swabbing[4]. However, in a study using electron microscopy of wound biopsies, James et al[13] demonstrated the existence of biofilms in 30 of 50 chronic wounds, and in only one of 16 acute wounds.

The concept of biofilms may help to explain many clinical challenges and why wound care can be difficult and unpredictable[14]. Wolcott et al[15] has proposed the concept of wound biofilm management as a method to manage infection, involving regular debridement to aid in the removal and suppression of biofilms[4].

How does Prontosan® support WBP?

Wounds may require cleansing if there is excess or problematic exudate, when there is slough and necrotic tissue or foreign material such as dirt and debris in the wound, or the wound is obviously infected.

Although water may be used as a wound cleanser, and has not been seen to increase the risk of infection or delay healing[16], the use of specifically designed wound cleansing agents may have the potential to improve clinical outcomes through their additional wound cleansing modalities[9]. Evidence is emerging that the combination of PHMB with a surfactant (betaine) has an increased ability to penetrate difficult-to-remove coatings, lifting debris, bacteria and biofilm from the wound[17].

How does Prontosan® work?

Role of polyhexamethylene biguanide

PHMB is a synthetic compound that has been in use for more than 60 years in various forms, including contact lens cleaners, mouth-washes, and more recently in wound management products, to

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reduce surface bioburden. It has demonstrated good clinical safety with no evidence of resistance and minimal toxicity[18,19].

It has been suggested that PHMB is structurally similar to naturally occurring antimicrobial peptides (AMPs)[20]. AMPs are produced by most living organisms and have a broad spectrum of activity against bacteria, viruses and fungi[18]. They are positively charged molecules that bind to bacterial cell membranes and induce cell lysis by destroying membrane integrity. PHMB is thought to work by breaking down the lipopolysaccharide layer (LPS) of the bacteria cell wall to kill bacteria[21]. This action is quick and so bacteria are unlikely to develop resistance to PHMB[22].

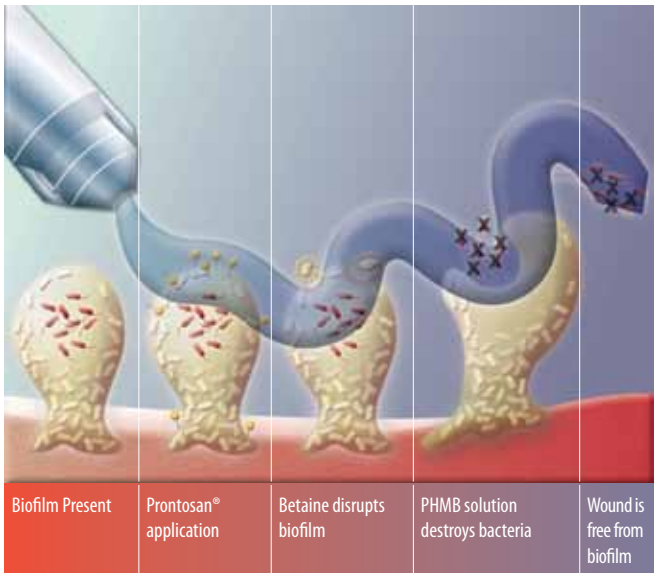
Role of betaine

Betaine is an amphoteric alkaloid surfactant that has a very mild action making it suitable for dermatological use. On a molecular level, betaine has a water-loving 'head' that is attracted to water molecules, and a hydrophobic water-hating 'tail' that repels water and attracts dirt and debris. The hydrophilic head remains in the solution, pulling the dirt and debris away from the wound and causing it to become suspended in the irrigating fluid enabling it to be flushed away.

As a result of its betaine (surfactant) component, Prontosan® has a lower surface tension than that of water, making it a more efficient cleanser. Many wounds are coated with denatured proteins, lipoproteins and lipids from cell membranes and carbohydrates. As these compounds denature (break down) they lose their solubility and coat the wound surface. The resulting low surface tension induced by the surfactant supports the physical removal of debris and bacteria[17] (Figure 1).

Betaine also interferes with the production of homoserine lactone, a signalling molecule used in the cell-to-cell communication of biofilms (known as quorum sensing), which play a role in biofilm pathogenicity[23]. The ability of betaine to disrupt biofilms is particularly beneficial as biofilms are now known to be resistant to cleansing with normal saline, which simply glides over the biofilm without removing it.

Figure 1 Role of Prontosan® in the disruption and removal of biofilm



What is the evidence for the use of Prontosan®?

Several *in vitro* and *in vivo* studies compare the use of Prontosan® with other sterile wound cleansing solutions. An *in vitro* study[24] found that Prontosan® was more effective at removing wound coatings when compared to four sterile wound cleansing solutions. Prontosan® was the only solution where the test coatings disintegrated and the denatured proteins solubilised[24]. This is supported by clinical evaluations that have reported increased healing rates and reduced incidence of wound infection (Table 1).

How safe is Prontosan®?

In an *in vitro* study to compare five commonly used skin antiseptics, all agents displayed effective antibacterial properties with Prontosan® and Lavasept showing the best test results. Prontosan® inhibited bacterial proliferation at the lowest concentration and demonstrated little cell toxicity at high concentrations[25]. It exhibited no adverse effect on fibroblast proliferation (cells vital to the wound healing process) at any concentration.

PHMB has been found to have no known toxic risks[18] and a low risk of sensitivity on contact[26,27]. Thus, Prontosan® has a low allergic potential and can be used on sensitive or irritated skin. Studies have also shown that Prontosan® is easy to use, has resulted in greater patient comfort at dressing changes and can be used long term[9, 17, 28].

Both the irrigation solution and the gels are sterile, colourless, odourless, ready-to-use products. They can be used in combination with all standard and advanced dressings (except larval therapy), and can be directly applied from the bottle or pod, or on a wet compress.

Unlike systemic antibiotics, Prontosan® does not interfere with protective bacterial flora in other parts of the body, such as the gut, and can be used as an alternative to antibiotic prophylaxis in surgical wounds for the prevention of surgical site infections[18].

When is Prontosan® indicated?

Prontosan® can be used on a variety of acute and chronic wounds, including:

- **Surgical and traumatic wounds**
- **Leg ulcers**
- **Pressure ulcers**
- **Diabetic foot ulcers**
- **First and second degree burns.**

The primary indication for using Prontosan® products is to cleanse, decontaminate and aid removal of excess exudate, slough and eschar, to prevent formation of biofilm and reduce wound odour.

Prontosan® Wound Gel can be applied to sutured surgical or traumatic wounds to prevent further microbial contamination. Both the irrigation solution and gels may also be used on fistulae, abscesses and undermining wounds. Prontosan® Wound Irrigation Solution can be used for entry sites of urinary catheters, PEG/PEJ tubes and stomas.

Prontosan® may provide a useful alternative or adjunct to systemic antibiotics and can also be used prophylactically as a method of WBP as there is no evidence of systemic absorption, toxicity or bacterial resistance to its components[18, 29, 30].

How to use Prontosan®

Step 1: Remove dressings prior to application

If required, warm Prontosan® Wound Irrigation Solution to body temperature immediately prior to use. Remove old dressings, using Prontosan® Wound Irrigation Solution to pre-soak and loosen encrusted dressings if necessary.

Step 2: Apply the solution

The wound and surrounding skin should now be irrigated with the solution to loosen surface debris and decontaminate. Although it may be used purely as a cleansing/irrigation solution, it is recommended that gauze pads be soaked in the solution and applied to the affected area for 15 minutes, or according to local protocols.

The wound area and surrounding skin can then be gently wiped with Prontosan®-soaked gauze to facilitate removal of surface debris and contaminants, biofilm, and devitalised tissue.

Table 1 Summary of evidence of Prontosan®

Study reference	Title	Type	Purpose	Outcomes
Perez R et al. *Wund Management* 2010; 4(2): 44-8[47]	Effect of different wound rinsing solutions on MRSA biofilm in a porcine wound model	Animal study	To evaluate activity of Prontosan® on MRSA and biofilms in a partial thickness porcine wound model, against untreated control	Significant reduction of MRSA at 48 and 72 hours ($p<0.05$) compared to the other treatment groups. Removal of MRSA biofilm was only demonstrated using Prontosan®; both saline solutions failed to reduce MRSA counts
Romanelli M et al. *Skin Pharmacol Physiol* 2010; 23 (Suppl 1): 41-4[43]	Evaluation of the efficacy and tolerability of a solution containing propyl betaine and polihexanide for wound irrigation	Single centre, prospective, controlled, explorative comparison trial (n=40)	To evaluate the efficacy and tolerability of Prontosan® in controlling bacterial burden in colonised, critically colonised and infected venous leg ulcers	Prontosan® group (n=20) showed a significantly better control of bacterial burden versus those treated with saline at each dressing change. It was well tolerated and useful in the absorption of wound odours
Moller A et al. *Wund Management,* 2008; 3: 112-7[28]	Experiences with the use of polyhexanide-containing wound products in the management of chronic wounds — results of a methodical and retrospective analysis of 953 patients	Retrospective study (n=953)	To assess the efficacy of PHMB-containing wound products in wounds of various aetiologies	Wound infection rate fell from 40% to 3% and 80% of the patients in the group with good cleansing results and improved findings achieved wound closure
Valenzuela AR, Perucho NS. *Rev ROL Enf* 2008; 31(4): 247-52[48]	The effectiveness of a 0.1% polyhexanide gel	Observational study (n=78 Prontosan® vs n=64 control)	Evaluation of the use of Prontosan® Gel in chronic wounds	Prontosan® Gel was found to reduce bioburden ($p=0.004$) and to aid wound healing, reducing the time to closure
Horrocks A. *Br J Nurs* 2006; 15(22): 1222–8[31]	Prontosan® wound irrigation and gel: management of chronic wounds	Observational study (n=10)	To evaluate the use of Prontosan® in chronic wounds	Prontosan® was found to provide a more efficient method of cleansing hard to heal wounds than normal saline
Andriessen AE, Eberlein T. Assessment of *Wounds* 2008; 20(6): 171-5[17]	Assessment of a wound cleansing solution in the treatment of problem wounds	Retrospective review (n=59 vs n=53 controls)	To assess the clinical efficacy and cost effectiveness of using a wound antiseptic to treat venous leg ulcers	Infection rates were reduced to 3% in the Prontosan® group compared to 13% in control group using normal saline/Ringer's solution. Prontosan® group healed quicker (3.31 months) compared to controls (4.42 months)

Step 3: Apply the wound gel

The solution may be used independently, but for best results it is recommended to use it in conjunction with Prontosan® Wound Gel or Prontosan® Wound Gel X. This allows wound cleansing and decontamination to continue, and maintains a moist wound healing environment until the next dressing change.

Prontosan® Wound Gel may be directly applied to the wound, filled into wound cavities or dressings can be moistened with the gel prior to application. The intention is to coat the wound copiously with the gel, although this may require review if the wound or surrounding skin becomes overly wet or macerated. It is recommended that in deep or tunnelling wounds and wound cavities a thick layer of Prontosan® Wound Gel is applied; in wounds with a large surface area, a layer of Prontosan® Wound Gel X should be applied.

Step 4: Apply secondary dressing

A secondary dressing should then be applied over the gel. The choice of secondary dressing will depend on the wound type and position, levels of exudate and frequency of dressing changes.

The gel may be used in conjunction with many types of secondary dressing, including non-adherent dressings/gauzes, absorptive fibrous dressings, foams and adhesive dressings. However, when used with absorptive products an increased amount of gel may be required to keep the wound bed moist as some will be absorbed into the secondary dressing. It is also suitable for use with a secondary dressing under compression bandaging.

How frequently should Prontosan® be used?

Where possible, it is advised to use Prontosan® daily at first, although improvements have been observed with less frequent dressing changes[31].

The wound irrigation solution and gel products can both be kept for up to eight weeks for single patient use once opened as long as there is no direct wound contact (except for the smaller ampoules of solution which are single use).

When to discontinue treatment

Recent guidelines suggest antiseptic agents should be discontinued when there are consistent signs of wound healing and no further signs of local infection[32,33].

However, Prontosan® is used primarily as a wound cleanser to facilitate removal of surface debris. It can therefore be used for much longer periods as a prophylactic treatment or until the wound maintains a clean and healthy granulating bed without evidence of biofilm.

It is important that such wound treatments are not used indiscriminately, especially if they have bactericidal properties; it is good practice to review the treatment plan after 14 days if the wound condition remains unchanged.

Prontosan® case study

Mr L is a 24-year-old male with spina bifida and is wheelchair-bound. The patient had no other significant medical history and was not on any medication. He had had a Grade 3-4 sacral pressure ulcer seven years previously, which had healed.

On presentation

Mr L presented with a Grade 3 pressure ulcer to his right ischial tuberosity of approximately six months' duration. All appropriate pressure-relieving equipment was in place, although he was known to sit for long periods of time. The wound measured 4.8cm x 3.3cm x 0.4cm with 0.5cm of undermining *(Fig 1)*.

Treatment

After five months of various topical treatments, including protease-modulating matrix dressings both with and without silver, absorptive fibrous dressings and honey ointment, the wound had deteriorated in size to 6cm x 4cm, with a depth of 1-2cm and undermining of 1.5cm. Mr L was assessed by a local pressure ulcer prevention and intervention service, who performed pressure mapping, reset the inflation of his pressure-relieving cushion and advised sitting periods of two to three sessions of two hours.

Despite these interventions, after a further three months the linear dimensions of the wound remained static with increased slough at its base. The depth had decreased to 0.2cm and undermining was now 0.7cm. Due to the chronicity, size and location of the defect it was becoming increasingly unlikely that it would heal by secondary intention. The long duration of the wound also made critical colonisation/localised infection a significant consideration as a contributor to non-healing.

The use of Prontosan® Irrigation Solution and Prontosan® Wound Gel were commenced to manage bioburden, remove devitalised tissue and stimulate healing. The ulcer and surrounding skin was cleansed with gauze soaked with Prontosan® Irrigation Solution for 15 minutes before Prontosan® Wound Gel was applied to the wound bed in conjunction with a fibrous dressing and adhesive dressing to secure. Dressing changes were recommended on alternate days as wound exudate was moderate to minimal.

Results

After six weeks of treatment with Prontosan®, the wound bed looked clean and healthy with signs of epithelialisation at the wound edges. Undermining had decreased to 0.3cm. After a further six months, the wound was significantly smaller at 3.3cm x 0.8cm with a depth of only 0.1cm and no undermining. Mr L was discharged to the community team at this point for follow-up until healed.

Mr L had previously been referred to the plastic surgeons for possible flap reconstruction surgery due to the non-healing state of the wound. This surgery was not required after using Prontosan® to address the issues of bioburden and debridement of unhealthy tissue. He was however referred again to plastic surgery for possible revision of the scar tissue remaining after healing due to the increased risk of re-ulceration.

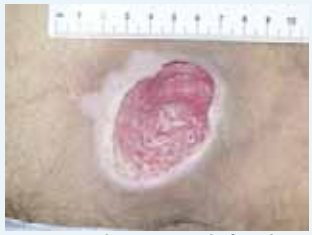


Fig 1: Wound appearance before the application of Prontosan®

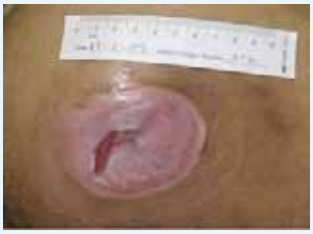


Fig 2: Improvement in the wound after seven months

When is Prontosan® contraindicated?

Prontosan® should not be used on anyone with a known or suspected allergy to betaine or PHMB. It is contraindicated for use on the central nervous system or meninges, middle or inner ear, eyes or on hyaline cartilage during surgery. Prontosan® should not be combined with other wound cleansers or ointments.

Although Prontosan® is unlikely to cause harm as it is not absorbed systemically, it should only be used in pregnant or lactating women or babies and infants under medical supervision due to lack of appropriate clinical trials.

What are the clinical advantages of using Prontosan®?

Prontosan® can be applied directly to many different wound types without further preparation. It is easy and simple to use even for patients and carers performing dressing changes themselves, providing it is reviewed regularly by a healthcare professional.

The gel formulation of Prontosan® can be left in place between dressing changes. It can also absorb exudate or donate moisture and is especially effective for wound cavities and difficult to reach areas. Any remaining gel will be removed by irrigation at the next dressing change.

Chronic wounds often cause patients to be sensitive to temperature. Prontosan® Wound Irrigation Solution can be warmed to body temperature in a baby-bottle heating device. This can make the dressing change procedure more comfortable for the patient and reduce wound pain[34,35].

A treatment that can contribute to pain-free dressing changes can help to reduce patient anxiety and the pain experienced[36-41]. In a 10-patient evaluation, Horrocks[31] reported that all of the patients said that the wound pain they experienced was either totally eliminated or considerably reduced when wounds were cleansed with Prontosan® Wound Irrigation Solution.

Encrusted dressings also pose a challenge to clinicians, as their removal will cause considerable pain to the patient. By intensely moisturising wound dressings with Prontosan® Wound Irrigation Solution, they can be gently released without causing trauma to the wound surface.

A particular benefit of Prontosan® is that both the solution and gels can be used in conjunction with many commonly used wound dressings. This means clinicians are not restricted to any particular dressing carrier and can choose a secondary dressing that is most suitable for the patient's wound type, position and level of exudate.

Impact on wellbeing and economic burden

Using Prontosan® to prevent increased bioburden may help to improve quality of life due to reduction in wound infections, wound pain and odour, factors that are known to affect mobility, sleep and social interaction and reduce quality of life in patients with wounds[42-45]. This may also lead to a reduction in the number of nursing visits required[31]. A potential reduction in surgical site infections may also impact on both quality of life and health economics by reducing length of hospitalisation, decreasing morbidity and mortality risk and decreasing treatment costs[46].

Summary

Prontosan® is a wound cleanser containing PHMB and betaine that is suitable for use on acute and chronic wounds. It is a safe and easy to use formulation consisting of a wound irrigation solution and gel that is applied to wounds to moisten, decontaminate and remove exudate, slough and debris.

Prontosan® provides an efficient and effective method of supporting wound bed preparation and removal of biofilm. Due to its good clinical safety, minimal cell toxicity and no evidence of bacterial resistance to its components, Prontosan® can provide an effective alternative to antibiotics and antimicrobial dressings as a method of controlling bacterial proliferation in wounds and preparing the wound for both primary and secondary closure.

To cite this publication

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For a more indepth look at biofilms, please see Biofilms Made Easy available from: www.woundsinternational.com

Healthcare practitioners are advised to consult the manufacturer's instructions before applying Prontosan® Wound Irrigation Solution and Gels. Further information at: www.prontosan-bbraun.com

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