

# Prontosan<sup>®</sup>

Wound bed preparation.  
Taken seriously.

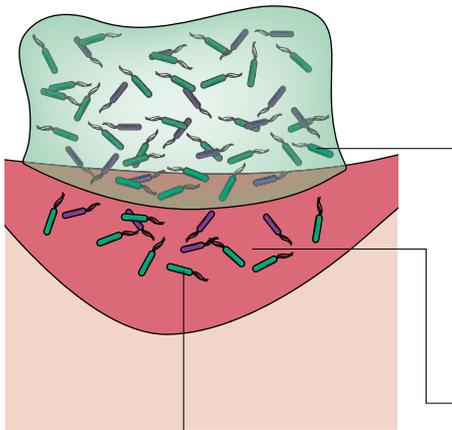


# The Problem: Biofilm

# 90<sup>0</sup>%

Traditional wound cleansing with saline or tap water can remove loosely adherent foreign material but is ineffective at removing coatings and debris in many wounds, especially complex biofilms.<sup>1</sup>

Over of chronic wounds have a biofilm present which is a major barrier to wound healing.<sup>2</sup>



## What is a biofilm?

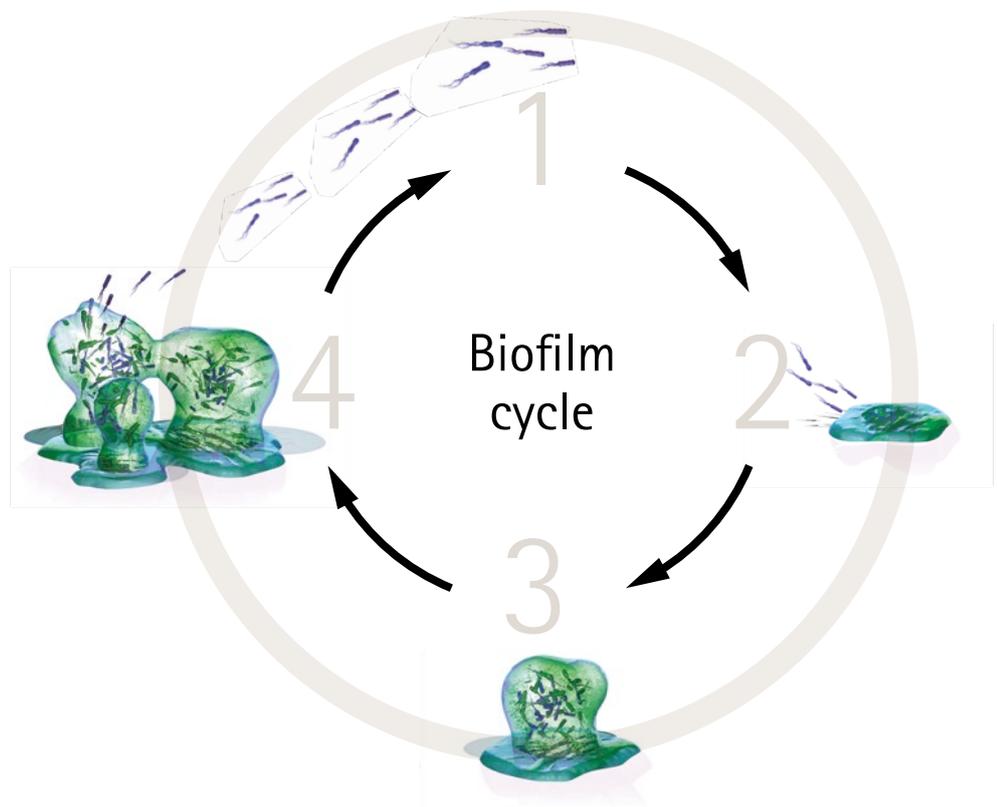
Biofilm forms when bacteria adhere to surfaces by excreting a thick, slimy, glue-like substance known as the Extracellular Polymeric Substance (EPS)<sup>3,4</sup>.

This substance forms a protective layer, where the bacteria are no longer free to move (planktonic), but adhere to the wound bed. A polymicrobial biofilm aggregate develops under the protection of the EPS.<sup>5</sup> Biofilms are often difficult to detect visually but they are an important factor hindering the healing of chronic wounds.<sup>6</sup>

Bacteria protected from topical agents in a biofilm  
Impaired migration and proliferation of keratinocytes  
Bacteria protected from systemic antibiotics

## How does biofilm develop?<sup>7</sup>

- 1 Contamination**  
Free floating bacteria attach to a surface within minutes. Initial attachment is reversible.
- 2 Colonisation**  
Bacteria multiply and become firmly attached within 2–4 hours.
- 3 Biofilm development and inflammatory host response**  
Develop initial EPS and become increasingly tolerant to within 6–12 hours.
- 4 Spreading leads to systemic infections**  
Mature biofilm releases bacteria within 2–4 days causing recolonisation, which results in a never ending biofilm cycle.



# The Solution: Prevention and management principles of biofilm

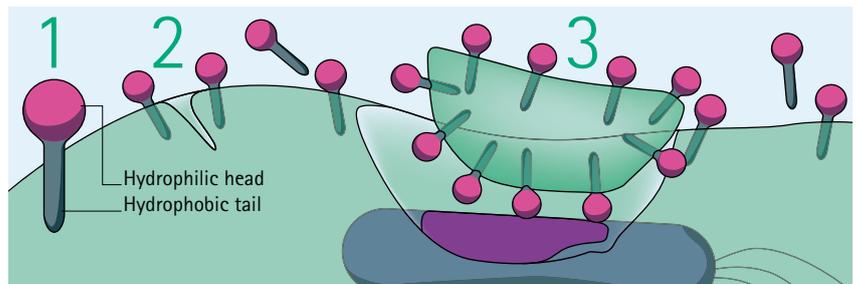
The prevention and management of biofilm in chronic wounds is rapidly becoming a primary objective of wound care, with the presence of biofilm acknowledged as a leading cause of delayed wound healing.<sup>6</sup>

**Prontosan® Wound Irrigation Solution and Prontosan® Wound Gel/Wound Gel X** are one of few products specifically indicated for the prevention and removal of biofilms. Prontosan® contains two key ingredients: **Betaine and Polyhexanide**.

## Mode of action of Betaine<sup>8</sup>

A gentle effective surfactant (detergent) which is able to penetrate, disturb, clean and remove biofilm and wound debris.

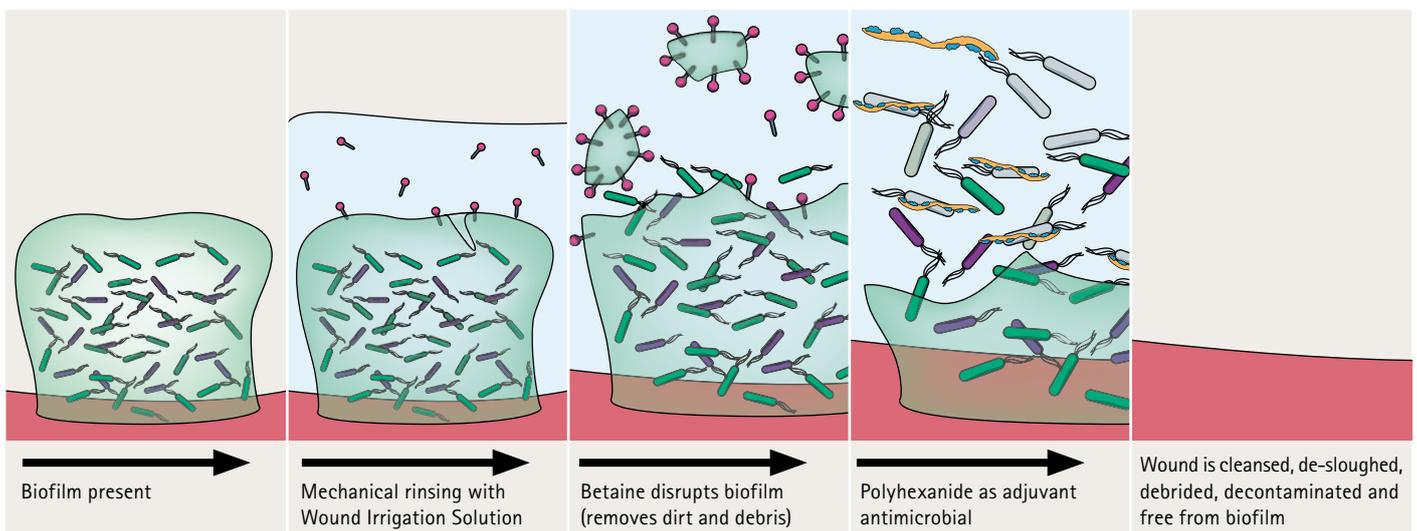
- 1 Betaine Molecule**  
Hydrophilic head remains in solutions.  
Hydrophobic tail is insoluble, detaches dirt/debris.
- 2 Reduces surface tension**  
Supporting softening, loosening and detaching of dirt, debris and biofilm
- 3 Removes and holds in solution**  
Holds dirt, debris and biofilm in the solution, preventing recontamination.



## Mode of action of Polyhexanide (PHMB)

### Promotes healing, minimises bioburden

Polyhexanide is a highly effective broad-spectrum antiseptic that is active against gram negative bacteria, including *Pseudomonas aeruginosa* and gram positive bacteria, including Methicillin resistant staphylococcus aureus (MRSA), Vancomycin resistant Enterococci (VRE), against yeast and others.<sup>9</sup> Polyhexanide has been in general use for about 60 years, it has demonstrated good clinical safety data (see overview page 5) with no evidence of resistance and very low toxicity.<sup>10</sup> Polyhexanide has low to no absorption by human cells and tissue, therefore interference with the metabolism of the body is negligible. Existing evidence shows that topical polyhexanide may promote healing of chronic stalled wounds, reduce bacterial burden, eliminate MRSA and alleviate wound related pain.<sup>11</sup>



# Prontosan<sup>®</sup> breaks the biofilm cycle

A proactive approach using a combination strategy of Prontosan<sup>®</sup> Wound Irrigation Solution and Prontosan<sup>®</sup> Wound Gel/Wound Gel X as part of wound bed preparation aims to:

- Reduce the biofilm burden  
(Prontosan<sup>®</sup> Wound Irrigation Solution)
- Prevent reconstitution of the biofilm  
(Prontosan<sup>®</sup> Wound Gel/ Wound Gel X ⓘ)

## Recommendations on soaking time and product combination

To achieve the best possible results, it may be useful to consider the individual condition of the wound.<sup>12</sup> The following recommendations are based on an observational study conducted in Italy.<sup>13</sup>

### Chronic Wound - Epithelialising

Cleanse - soak - cleanse with solution

- No slough
- Low exudate
- Highly fragile epithel tissue



- Cleanses the wound
- Helps to prevent biofilm



### Chronic Wound - Granulating

Cleanse - soak - cleanse with solution      Apply Gel/Gel X ⓘ

- Light slough
- Low/medium exudate



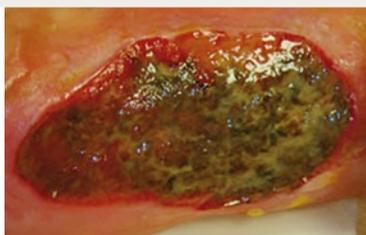
- Mechanically removes debris and slough (ideally use the Prontosan<sup>®</sup> Debridement Pad)
- Polihexanide has proven to promote wound healing\*<sup>7</sup>



### Chronic Wound - Exuding/Colonised

Cleanse - soak - cleanse with solution      Apply Gel/Gel X ⓘ

- Slough
- Medium/high exudate
- Stalled wound



- Mechanically removes debris and slough (ideally use the Prontosan<sup>®</sup> Debridement Pad)
- Polihexanide has proven to promote wound healing\*<sup>7</sup>
- Reduction of odor



ⓘ Apply Prontosan<sup>®</sup> Gel in wounds with cavities, deep or tunneling wounds and difficult to access areas, Prontosan<sup>®</sup> Wound Gel X on larger surface wounds.

\* in studies with Prontosan<sup>®</sup> Wound Irrigation Solution on Venous Leg Ulcers, Pressure Ulcers and Burns and with Prontosan<sup>®</sup> Wound Irrigation Solution & Prontosan<sup>®</sup> Wound Gel (X) on chronic wounds like Diabetic Foot Ulcers, Venous Leg Ulcers or Pressure Ulcers, Surgical Wounds and Burns.

# Clinical Evidence

| Study   | Type          | Conclusion  |
|---|---------------|---|
| Bellingeri A. et al. (2016). Effect of a wound cleansing solution on wound bed preparation and inflammation in chronic wound: a single-blind RCT, <i>Journal of Wound care</i>  | RCT           | The results of this RCT with 289 subjects confirms the superiority of Prontosan® Wound Irrigation Solution compared to Saline in efficacy as it promotes the wound bed preparation, supports the reduction of inflammatory signs and accelerates the healing of vascular leg ulcers as well as pressure ulcers.   |
| Romanelli M. et al. (2008). Evaluation of the efficacy and tolerability of a solution containing Betaine and PHMB in controlling the bacterial burden of chronic wounds during wound bed preparation                      | RCT           | The results of the RCT with 40 subjects show that the pH value of the wound was significantly ( $p < 0.05$ ) lower and that pain control was achieved ( $p < 0.05$ ) in the Prontosan treatment group compared to the Saline group which was the control.   |
| Valenzuela et al. (2008). The effectiveness of a 0.1% polyhexanide gel. <i>Rev ROL Enf</i> ;31(4):247-52.   | RCT           | Both groups were comparable at the start of the study and the results obtained in the final assessment of lesions were as follows: Reversal of positive cultures ( $p = 0.004$ ), improvement in the healing process ( $p = 0.000$ ), reduction in lesion surface area ( $p = 0.013$ ); improvement in granulated tissue % ( $p = 0.001$ ), reduction in the % of slough in wound beds ( $p = 0.002$ ), reduction of the presence of exudate ( $p = 0.008$ ), reduction of the presence of purulent exudate ( $p = 0.005$ ), improvement in the condition of surrounding skin ( $p = 0.021$ ), reduction in pain ( $p = 0.049$ ), reduction in erythema in surrounding skin ( $p = 0.004$ ), reduction in surrounding skin edema ( $p = 0.000$ ), reduction in surrounding skin warmth ( $p = 0.004$ ) and reduction in odor ( $p = 0.029$ ). |
| Cutting K. (2010). Addressing the challenge of wound cleansing in the modern era, <i>British Journal of Nursing</i> , 2010 (Tissue Viability Supplement), Vol 19, No 11   | Review        | If current thinking, that all chronic wounds are biofilm wounds (Wolcott and Rhoads, 2008), is sustained then we will need to rethink our approach to wound cleansing, as the studies examined above indicate that PHMB, in conjunction with a surfactant, is superior to isotonic solutions. In addition, there is evidence emerging that Prontosan is an effective wound cleanser in longstanding (chronic) wounds and has been found by patients to be pain-free, improve patient quality of life, effectively manage wound infection and to reduce the overall time to healing.   |
| Butcher M. (2012). PHMB: An effective antimicrobial in wound bioburden management, <i>British Journal of Nursing</i> (2012) 21:12 SUPPL. (16-21).   | Review        | PHMB appears to meet the criteria for an ideal antimicrobial agent, as described by Drosou et al (2003), and is available in presentations that provide clinicians with effective woundcare modalities for most clinical scenarios. Clinical use, both in the UK and the wider healthcare community, has shown PHMB-based wound-care products to be effective options for managing wound colonisation and infection and, so, deserve closer scrutiny.   |
| Dissemond J. et al. (2005). Methicilin-resistenter Staphylococcus aureus (MRSA) in chronischen Wunden, <i>JDDG</i>  | Review        | Sufficient MRSA eradication could be shown in vivo on patients for the non-cytotoxic Polyhexanide [...]. In this article we discuss current therapeutic standards and potential alternatives for eradication of MRSA. There is evident need for effective, novel approaches for elimination of MRSA from chronic wounds that avoid the development of bacterial resistance; otherwise therapeutic alternatives for antibacterial treatment of chronic wounds will become limited.   |
| Andriessen A, Eberlein T. (2008). Assessment of a wound cleansing solution in the treatment of problem wounds, <i>WOUNDS</i> ; 20(6):171-5  | Retrospective | Wounds (Venous leg ulcers) of patients treated with Prontosan® Wound Irrigation Solution healed significantly faster ( $p < 0.0001$ ) and in more cases (97% versus 89%) than the wounds of patients treated with saline solution or Ringer's solution. Additionally the infection rate for the Prontosan group was lower (13% vs. 3%)  |
| Moller et al. (2008). Experiences in using polyhexanide containing wound products in the management of chronic wounds – results of a methodical and retrospective analysis of 953 cases, <i>Wundmanagement</i> ; 3:112-7. | Retrospective | Treatment resulted in an improvement of 97% and a complete closure of 80% of the wounds. Infection rates declined from 40% to 3%. Prontosan® Wound Irrigation Solution and Gel were compatible with various wound dressings, induced no skin irritations, reduced odor and were accepted by the patients.   |
| Durante et al. (2014). Evaluation of the effectiveness of a polyhexanide and propyl betaine-based gel in the treatment of chronic wounds, <i>Minerva Chirurgica</i> ; 69(5):283-92  | Observational | The results of this observational study showed that the treatment of skin wounds of various kinds and types, in different ages, from pediatric age, until the geriatric age, with a polyhexanide and propyl betaine-based gel in combination with a secondary dressing showed significant improvements in the size of the wound, pain at dressing change, and wound characteristics.  |
| Kaehn et al. (2009). In-vitro test for comparing the efficacy of wound rinsing solutions, <i>British Journal of Nursing</i>   | In-vitro      | Saline solutions were less efficient than a betaine surfactant containing wound rinsing solution in removing protein from adherent test wound coatings. Salt ions hinder the hydration of proteins and decrease protein solubility. Prontosan® Wound Irrigation Solution solubilized denatured proteins and aggregated by inclusion in betaine surfactant micelles. This is an essential property for thorough and gentle wound cleansing. Wound progress of leg ulcers was more positive when the wound was treated with Prontosan® Wound Irrigation Solution compared with saline solution. The wound antiseptic Octenisept did not seem suitable for wound cleansing because proteins were denatured and became insoluble.   |
| Lopez-Rojas et al. (2016). In vitro activity of a polyhexanide-betaine solution against high-risk clones of multidrug resistant nosocomial pathogens, <i>Enferm Infecc Microbiol Clin</i> 35 (1), 12-9.                   | In-vitro      | Prontosan® Wound Irrigation Solution has high bactericidal activity against the studied multidrug-resistant pathogens. Furthermore, this bactericidal activity occurs rapidly (1 min), within a much shorter period of time than that recommended by the manufacturer.  |
| Hirsch et al. (2010). Evaluation of Toxic Side Effects of Clinically Used Skin Antiseptics In Vitro, <i>Journal of Surgical Research</i> Volume 164, Issue 2  | In-vitro      | Due to the cytotoxic effect of some antiseptics on human skin cells, it is advised that health care professionals balance the cytotoxicity of the medication, their antiseptic properties, and the severity of colonization when selecting a wound care antiseptic. Lavasept and Prontosan® Wound Irrigation Solution showed best result regarding antibacterial efficacy and cell toxicity, and should therefore be favored in clinical wound care.  |
| Seipp et al. (2005). Efficacy of various wound irrigants against biofilm, <i>ZFW</i> ; 4: 160-4.  | In-vitro      | As far as the clinical practice of biofilm removal based on moist management practices is concerned, our investigations attest to the superior efficacy of the surfactant and polyhexanide solution compared with isotonic saline or Ringer's solution.   |

# Wound bed preparation. Taken seriously.

The clinical evidence demonstrates that by routinely introducing a Prontosan® regime as part of your patient pathway you can achieve better result.

- Improved patient outcomes, including time to heal<sup>14</sup>
- Helps to prevent complications<sup>13,15</sup>
- Can help to reduce antimicrobials and antibiotics<sup>16</sup>

## How Prontosan® might save you money

In a model calculation for the UK, based on the average reduction in treatment time of patients with Venous Leg Ulcers, the cost saving from changing to the Prontosan® regime compared to saline is, on average, **£ 867.87** per patient over a time horizon of one year.<sup>17</sup>



| Breakdown of wound care costs <sup>18</sup> | Cost drivers  | How Prontosan® can help to reduce costs   |
|---|---|---|
| <b>40%</b> Inpatient costs                  | <ul style="list-style-type: none"> <li>• Increased number of hospital days</li> <li>• Complication rates</li> </ul> | <ul style="list-style-type: none"> <li>• Infection rates reduction with Prontosan® Wound Irrigation Solution &amp; Prontosan® Wound Gel*</li> <li>• Inflammatory signs reduced with Prontosan® Wound Irrigation Solution**</li> </ul>                         |
| <b>40%</b> Nursing time                     | <ul style="list-style-type: none"> <li>• Length of treatment time</li> </ul>  | <ul style="list-style-type: none"> <li>• Treatment reduction from 17 to 13 weeks with Prontosan® Wound Irrigation Solution***</li> <li>• Wound size reduction. BWAT Score p=0.049. Granulation tissue improvement. BWAT Score p=0.043<sup>14</sup></li> </ul> |
| <b>20%</b> Dressing                         | <ul style="list-style-type: none"> <li>• Cost of dressings</li> <li>• Frequency of dressing changes</li> </ul>      | <ul style="list-style-type: none"> <li>• Reduction in dressing change frequency of 55% in hard-to-heal wounds<sup>19</sup></li> </ul>   |

BWAT = Bates-Jensen Wound Assessment Tool

\* in Diabetic Foot Ulcers, Leg Ulcers, Pressure Ulcers, Radiotherapy damage (oncology patients).<sup>20</sup>

\*\* in Venous Leg Ulcers and Mixed Ulcers (BWAT Score p=0.0043).<sup>21</sup>

\*\*\* on Venous Leg Ulcers.<sup>22</sup>

**Helping compliance** | At B. Braun we recognize the benefits of implementing a standardised approach to providing a better level of care and outcome. When implementing a Prontosan® pathway we will support you by providing educational packages to ensure compliance and to support your required educational needs.

# Quality of life case study extracts

"The use of Prontosan® Wound Irrigation Solution and Wound Gel X contributed to the **speedy healing** of these diabetic wounds by reducing bioburden. Their use enabled the **painless** removal of sloughy tissue within one week. The patient spoke of **increased confidence** that his wounds would heal, directly as a consequence of using Prontosan®."

Butters V, McHugh J. A Case Report On The Use Of A Moistening, Cleansing, Surfactant Irrigation Solution And Gel On A Traumatic Wound On A Diabetic Patient In A Busy Acute Department. European Wound Management Association (2012): 481.



07/07/2010



03/09/2010

"The patients quality of life improved with a **reduction in pain and reduction in exudate level with Prontosan® Wound Gel in chronic wounds** requiring only weekly dressings. Her mobility increased and she could begin to walk short distances again, allowing her to go out and **resume normal social activities**. The cost of wound management was reduced with only weekly visits by district nurses being required, compared to daily visits prior to intervention, and through reduced use of antibiotics"

Ovens L. Removal Of Biofilm In Infected Venous Leg Ulcers Using Prontosan® Wound Irrigation Solution And Gel. European Wound Management Association (2010)



03/09/2009



10/12/2009

"The benefits in terms of **increased quality of life** for this patient cannot be underestimated and as a result of the **successful wound management** this lady has now started to swim again, is looking forward to a holiday abroad with friends and most importantly is now being considered for the renal transplant list."

Hughes N. Calciphylaxis – A Successful Outcome In Wound Management Using Prontosan. European Wound Management Association (2008)



01/04/2008



10/06/2008

"Historically, daily visits from the district nursing staff commenced in January 2001 and took one hour per day. Both the patient and his family found the visits a necessity but they felt that their lives revolved around treating the ulcers. Since commencing Prontosan®, visits from the district nurse were reduced to alternate days and the patient and his wife attended their son's wedding, with no detrimental effect to either ulcer. **This was the first time the patient had left his house to attend a social occasion for over 5 years.** It has made significant improvements to both wounds which the patient, his wife and district nursing service did not expect to see. This has **improved the patient's morale** and the results have motivated all nursing staff."

Horrocks A. Successful Treatment of two grade 4 pressure ulcers of 5 years duration using Prontosan® Solution and Gel. European Wound Management Association (2006)



12/04/2006



14/04/2006



17/02/2006



17/03/2006

# Prontosan® Wound Irrigation Solution and Wound Gel / Wound Gel X

## Ordering Information

| Product Description                  | Size           | Pack Size | Product Code |
|--------------------------------------|----------------|-----------|--------------|
| Prontosan® Wound Irrigation Solution | 40 ml ampoule  | 24        | 400484       |
|                                      | 350 ml bottle  | 10        | 400403       |
|                                      | 1000 ml bottle | 10        | 400446       |
| Prontosan® Wound Gel                 | 30 ml pod      | 20        | 400505       |
| Prontosan® Wound Gel X               | 50 g tube      | 20        | 400517       |
|                                      | 250 g tube     | 20        | 400508       |

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B. Braun Avitum AG | 34209 Melsungen | Germany  
Phone +49 5661 71-0 | [www.bbraun.com](http://www.bbraun.com)