



FREQUENTLY ASKED QUESTIONS

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

FAQ Prontosan® range

1. WHAT DO I HAVE TO KNOW ABOUT THE ANATOMY AND PHYSIOLOGY OF THE SKIN?

Being the largest human organ, the skin covers almost an area equivalent to 2 square meters and can weigh up to 10 kg. It serves as a protective barrier against the external environment while maintaining homeostasis internally. The skin is made up of two major layers, the epidermis and the dermis which rest on a fatty layer called hypodermis (subcutaneous tissue). The epidermis and dermis are in turn composed of sub-layers. The area that anchors the epidermis to the dermis is called the dermal-epidermal junction. It is responsible for the exchange of oxygen, nutrients and waste products between the vascularized dermis and the avascular epidermis.

The skin has many important functions:

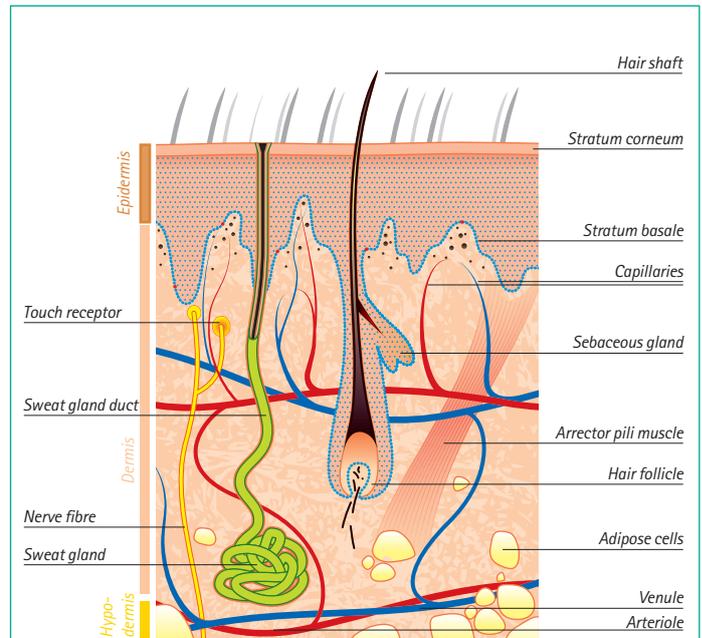
- **Social importance**
appearance and identification of a person
- **Protection**
protective barrier against the external environment such as chemical or mechanical injuries or ultraviolet radiation and maintenance of a homeostasis internally
- **Sensation**
sensitive to pain, touch, pressure and temperature
- **Thermoregulation**
thermoregulation through dilatation and constriction of vessels and sweating
- **Metabolism**
synthesis of Vitamin D (calcium and phosphate metabolism) in the presence of sunlight

2. WHAT IS A WOUND AND WHAT DIFFERENT TYPES OF WOUNDS EXIST?

The term wound is derived from the Latin word «vulnus» and can be defined as a compromising of integrity of any living tissue (e.g. skin) with or without tissue loss. A wound can result accidentally from a traumatic injury or intentionally from a surgical procedure. Wounds can be classified by their origin:

- Mechanical
- Thermal
- Chemical
- Radiation
- Skin ulceration

Anatomy of the skin



3. HOW DOES A WOUND HEAL?

Wound healing is a complex and dynamic process that ideally leads to restoration of anatomic continuity and function. The entire process is a series of overlapping events that begins at the moment of the injury and can last for days to months, and, for some chronic wounds, even years. The wound healing process can be divided into three phases: (1) Inflammation, (2) Proliferation and (3) Remodelling.

4. WHAT IS THE DIFFERENCE BETWEEN AN ACUTE AND A CHRONIC WOUND?

Acute wounds are typically traumatic or surgical in origin. Usually, these wounds occur suddenly, move rapidly through the wound healing process and ideally lead to normal wound closure without causing major complications. Examples of acute wounds are lacerations, animal bites or stab wounds. Chronic wounds are those with delayed healing. In chronic wounds the healing process is stuck in one (most frequently, inflammatory) phase. Chronic wounds have characteristic features and compared to acute wounds, they fail to heal in a timely and orderly manner. The vast of chronic wounds can be classified into three major categories: venous ulcers, diabetic, and pressure ulcers.

5. WHAT IS THE CLASSIFICATION STATUS OF PRONTOSAN®?

Prontosan® Wound Irrigation Solution, Prontosan® Wound Gel and Prontosan® Wound Gel X have a marketing authorisation as Class III medical devices, based on the EU Medical Device Directive 2007/47/EC (MDD).

In order to get an approval, class III devices require design/clinical trial reviews, product certification and an assessed quality system. All third-party product and system certification must be conducted by a European Notified Body (or its designee through formal agreement).

6. WHAT IS PRONTOSAN® MADE OF?

All Prontosan® products contain a betaine surfactant, polihexanide (PHMB) and purified water. Additionally, Prontosan® Wound Gel and Prontosan® Wound Gel X contain glycerol and hydroxyethylcellulose.

7. WHAT ARE THE ADVANTAGES OF PRONTOSAN®?

Prontosan® – The unique combination of Betaine and Polihexanide

- reduces healing time
- removes and prevents biofilm
- prevents infections
- facilitates gentle dressing changes
- is compatible with commonly used dressings

8. WHICH TYPE OF WOUNDS CAN BE TREATED WITH PRONTOSAN®?

Prontosan® can be used for the treatment of acute wounds, chronic wounds and 1st and 2nd degree burns (Prontosan® Wound Gel X is also indicated for 3rd degree burns).

9. DOES PRONTOSAN® HELP WITH DEBRIDING, AND IF SO HOW?

Yes. Betaine helps to remove wound coatings including slough and necrotic tissue by softening, loosening and subsequently detaching them.

10. HOW TO USE PRONTOSAN®

Prontosan® Wound Irrigation Solution

- Squeeze directly from the bottle to remove already loose wound coatings.
- Wet a compress and leave it on the wound for 10 – 15 minutes, or per your facility's protocol, to soften and loosen wound coatings. Subsequently, the loosened material can be washed away with Prontosan®.

Prontosan® Wound Gel and Prontosan® Wound Gel X

- Apply the Gel after cleansing the wound with Prontosan® Wound Irrigation Solution. The Gel is a «leave on» product and will create a film on the wound bed. This ensures softening of hard-to-remove coatings. Leaving the Gel on the wound provides a «continuous» coverage. The choice between Prontosan® Wound Gel and Gel X allows an optimal application in large surface area as well as deep wounds.

11. WHAT PRESSURE IS GENERATED BY SQUEEZING THE PRONTOSAN® WOUND IRRIGATION SOLUTION BOTTLE (350 ML)?

The liquid, squeezed out of the 350 ml bottle generates up to 7 PSI (pounds per square inch) of pressure. According to a Medtech Insight 1997 (Chapter 3, pp 71 – 72) report, a PSI between 4 – 15 is required for adequate wound irrigation and cleansing. Spray bottles can generate only up to 1.5 PSI. Prontosan® does not need to be transferred to another container (such as a syringe) to produce adequate PSI pressure.

12. FOR HOW LONG CAN A WOUND BE TREATED WITH PRONTOSAN®?

There is no limit set for the treatment duration with Prontosan® Wound Irrigation Solution. In clinical trials, the longest documented treatment duration was 58 days. In fact, Prontosan® is especially designed for the long term treatment of hard-to-heal wounds.

13. HOW EXTENSIVE IS THE CLINICAL EXPERIENCE WITH PRONTOSAN®?

Hundreds of thousands of patients were treated with Prontosan® in Europe in the last years. In the US patients have got an access to Prontosan since 2009. A dedicated Scientific Evidence Brochure has been created to document the efficiency and efficacy of Prontosan®.

14. WHAT IS THE SHELF LIFE OF PRONTOSAN® PRIOR TO OPENING?

Prontosan® Wound Irrigation Solution, Prontosan® Wound Gel and Prontosan® Wound Gel X have a shelf life of 3 years.

15. WHAT IS THE SHELF LIFE OF PRONTOSAN® AFTER FIRST OPENING?

8 weeks for the whole Prontosan® product range.

Important: Prontosan® does NOT need to be refrigerated to maintain shelf life. It can be warmed up to body temperature before using.

16. HOW IS PRONTOSAN® PACKAGED?

Prontosan® Wound Irrigation Solution is produced using a «blow, fill, seal» process. In a single step, each container is blown into its given size and shape, filled with Prontosan® before being sealed completely. The Prontosan® 350 ml and 1000 ml bottles feature a special safety protection. It is a spike, integrated into the inside of the cap. First, the cap has to be unscrewed, then the white collar ring must be removed prior to putting the cap back on and screwing it tight. This way, the spike pierces the bottle's sealing and the product is ready for application. To open the 40 ml Solution as well as the 30 ml Gel ampoules just turn the toggle closure. The Prontosan® Wound Gel X originality seal can be opened by utilizing the cast counterpart in the cap.

17. ARE PRONTOSAN® CONTAINERS AND LABELS ENVIRONMENTALLY FRIENDLY?

Yes. Prontosan® containers and labels are PVC-free, DEHP-free as well as latex-free.

18. HOW DO WE ANSWER TO THE STATEMENT OF ECHA THAT PHMB MAY BE CANCEROGENIC?

PHMB is widely used in commercial and industrial settings. It has a long history of safe clinical use (> 40 years), among other medical applications in surface devices for wound management. The safety of medicinal products, surface devices for wound management containing polyhexanide is not affected by the classification of the raw material PHMB. The approval status of drugs and medical devices remains unaffected by this classification. In accordance with their intended use, these products contain only small amounts of polyhexanide, normally between 0.02 % and 0.3 %. Prontosan® products which are surface devices for wound management contain only 0.1 % polyhexanide.

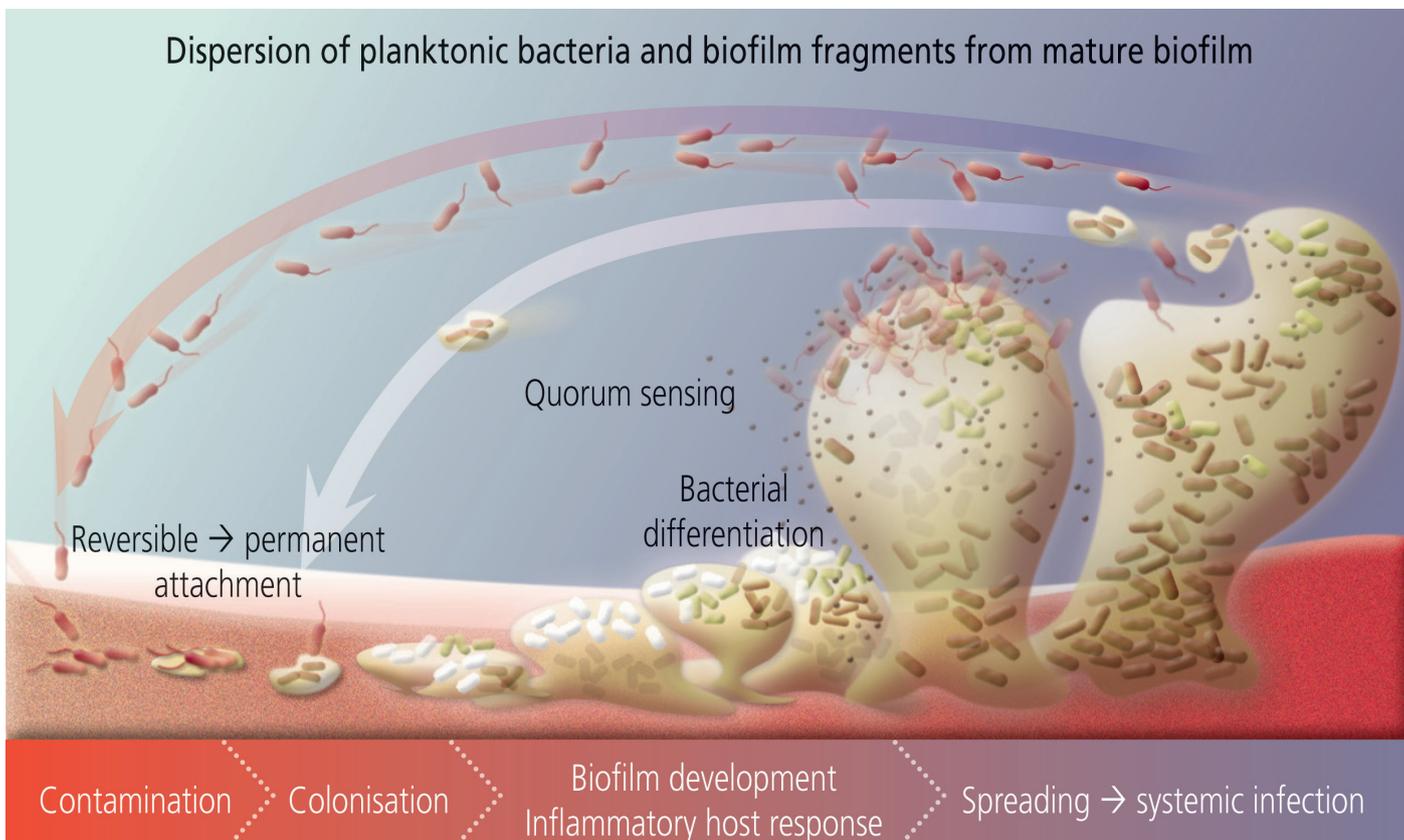
A wider application in medicine has only been possible since a particularly pure form of PHMB, polyhexanide, has been available, which has significantly limited the overall profile of contaminants and related substances and optimised the oligomer distribution.

B. Braun uses only this highly purified form for its preparations and has made some parameters even stricter in order to ensure the highest possible level of safety for the preparations Prontosan®, Prontoderm® and Lavasept®.

A more detailed statement can be requested by your local marketing contact.

19. WHY CAN'T WE CLAIM ANTIMICROBIAL ACTIVITY OF PRONTOSAN®?

Prontosan® is a medical device class III and used as a debridement solution or wound dressing (Gel). The combination of betaine (surfactant) and PHMB improves the functionality of intended use. The main purpose is cleansing the wound, remove the biofilm and prevent the formation of new one. PHMB is used as an adjuvant agent and as a preservative.



20. IS PRONTOSAN® WOUND IRRIGATION COMPATIBLE WITH SILVER-DRESSINGS?

Yes, Prontosan® Wound Irrigation can be used with Silver Dressings. Studies (e.g. Moller et al (2004). 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, K2 Hygiene Services, Municipal Hospital Bilfeld, Aschaffenburg, Germany) and Test reports (Test report on File – Brill L13/0111.1 – can be requested by our local marketing) document no degradation of functionality of both the irrigation solution or the dressing.

21. CAN PRONTOSAN WOUND IRRIGATION BE USED FOR ORTHOPAEDIC SURGERIES?

Yes. Several users reported good clinical results in using Prontosan® as rinsing solution for orthopaedic surgeries (case reports). Care has to be taken in case of partial joint replacement where intact hyaline cartilage is still present (contraindication). For total joint replacements (hip and knees) the cartilage is completely removed and therefore the use of Prontosan® is possible.

For more information please visit the website:
www.woundcare-bbraun.com

Prontosan® range

22. WHEN TO USE WHICH GEL?

1. For the application in deep or tunneling wounds, wound cavities and difficult to access areas, cover the entire area with a 3–5 mm layer of Prontosan® Wound Gel and apply a secondary bandage.
2. On large surface area wounds apply a 3–4 mm thick layer of Prontosan® Wound Gel X and cover with a secondary bandage.

For additional information, please read the Prontosan® instruction for use.



Prontosan® Wound Gel, Fluid

- For deep and tunneling wounds, wound cavities as well as for difficult to access wounds.
- For burn wounds I. & II. degree.



Prontosan® Wound Gel X, Highly viscous gel

- For wounds with extensive surface area, e.g. Ulcus cruris or Decubitus.
- Where Prontosan® Wound Gel is too fluid and may easily drip out of the wound surface.
- For all burn wounds.

250 g Tube

- For large surface area wounds.
- For repeated use (same patient).



50 g Tube

- Smaller surface area wounds where small quantity is required.
- If a single application for large wounds is required.
- Ambulatory & Home Care.

B. Braun Medical AG | Infection Control | Seesatz 17 | CH-6204 Sempach
Phone +41 58 258 50 00 | Fax +41 58 258 60 00 | info.bbmch@bbraun.com | www.bbraun.com