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

Frequently Asked Questions
1. Q: What do I have to know about the anatomy and physiology of the skin?
A: 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. Mean absolute reduction in wound size per group.

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. Q: What is a wound and what different types of wounds exist?
A: The term wound is derived from the Latin word «vulnus» and can be defined as a disruption in the normal continuity of a body structure (e.g. skin) with or without tissue loss. A wound can accidentally result from a traumatic injury or intentionally from a surgical procedure. Wounds can be classified by their origin:
- Mechanical
- Thermal
- Chemical
- Radiation
- Skin ulceration

3. Q: How does a wound heal?
A: 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 months to years. The wound healing process can be divided into three phases: (1) Inflammatory, (2) Proliferation and (3) Remodelling.

4. Q: What is the difference between an acute and a chronic wound?
A: 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 can be described as a wound in which the normal wound healing process is stuck in one (usually inflammatory phase) or more points of the wound healing phases. Chronic wounds have characteristic features and compared to acute wounds, they fail to heal in a timely and orderly manner. The vast majority of chronic wounds can be classified into three categories: venous ulcers, diabetic, and pressure ulcers.
5. Q: What classification of product is Prontosan®?
A: Prontosan® Wound Irrigation Solution, Prontosan® Wound Gel and Prontosan® Wound Gel X are categorized as Class III medical devices, based on the EU Medical Device Directive 2007/47/EC (MDD). 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 designee through formal agreement).

6. Q: What is Prontosan® made of?
A: The Prontosan® product range contains a Betaine surfactant, Polihexanide (PHMB) and purified water. Additionally, Prontosan® Wound Gel and Prontosan® Wound Gel X contain glycerol and hydroxyethylcellulose.

7. Q: What are the advantages of Prontosan®?
A: Prontosan® – The unique combination of Betaine and Polihexanide
- reduces healing time
- removes and prevents biofilm
- prevents infections
- facilitates painless dressing changes
- is compatible with commonly used dressings

8. Q: Which type of wounds can be treated with Prontosan®?
A: 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 and 4th degree burns).

9. Q: Does Prontosan® help with debriding, and if so how?
A: Yes. Betaine helps to remove wound coatings including slough and necrotic tissue by softening, loosening and subsequent detachment.

10. Q: What is the procedure/protocol for use?
A: 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.

When to use which gel

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<thead>
<tr>
<th>Prontosan® Wound Gel</th>
<th>Prontosan® Wound Gel X</th>
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<tbody>
<tr>
<td>30 ml pod Fluid</td>
<td>250 g tube Highly viscous</td>
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<tr>
<td>For smaller, deep and tunneling wounds, as well as for difficult to access wounds</td>
<td>For large surface area wounds, e.g. Ulcus cruris, Decubitus</td>
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<tr>
<td>For burn wounds I. &amp; II. degree</td>
<td>For all burn wounds, incl. III. &amp; IV. degree</td>
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<tr>
<td>If little quantity is required</td>
<td>When large quantities are required</td>
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<tr>
<td>Where Prontosan® Wound Gel is too fluid</td>
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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 cover with 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.
11. Q: What Pounds per Square Inch (PSI) is generated by squeezing the Prontosan® Irrigation Solution bottle (350mL)?
A: The PSI for the 350 ml bottle is up to 7 PSI. According to research reported in Medtech Insight 1997 (Chapter 3, pp 71 – 72), a PSI between 4 -15 is required for adequate wound irrigation and cleansing. Spray bottles only produce up to 1.5 PSI. Prontosan® does not need to be transferred to another container (like a syringe) to produce adequate PSI.

12. Q: What is the length of time that Prontosan® can be used to treat wounds?
A: There is no limit to the length of time that Prontosan® can be used in the treatment of wounds. In fact, Prontosan® is especially designed for the long term treatment of hard-to-heal wounds.

13. Q: How long has Prontosan® been available?
A: Prontosan® has been sold in Europe for several years and was made available in the US in September 2009.

14. Q: How does Prontosan® compare to other wound cleansing agents on the market?
A: There is no other wound cleansing agent on the market featuring the combination of Betaine and Polihexanide (PHMB)

15. Q: What is the shelf life of Prontosan® prior to opening?
A: Prontosan® Wound Irrigation Solution and Gel: 3 years
Prontosan® Wound Gel X: 2 years

16. Q: What is the shelf life of Prontosan® after first opening?
A: 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.

17. How is Prontosan® packaged?
A: Prontosan® Wound Irrigation Solution is produced using a «blow, fill, seal» process. The production line «blows» the plastic material into the designated size container, and then the containers are «filled» with Prontosan® before being «sealed» completely.
Other than the single use 40 ml vial size, the Prontosan® 30 ml, 350 ml and 1000 ml containers can not be used until the spike, integrated into the top inside of the cap, pierces the container by screwing the cap tightly on to the container in a clockwise motion. The white ring collar on the 350 ml and 1000 ml container must be removed prior to tightening the cap. To open the Wound Gel X tube use the cap to break the originality seal.

18. Are Prontosan® containers and labels environmentally friendly?
A: Yes. Prontosan® containers and labels are PVC-free, DEHP-free as well as Latex-free.

More information can be found on www.prontosan-bbraun.com