

Prontosan® Wound Irrigation Solution



Read instruction for use.



Single use only



Use by: month and year



Keep out of reach of children.



Shelf life after opening: 8 weeks.



Batch number



Catalog number



Sterile A



Keep bottles out of direct sunlight.



Manufacturing date



Manufacturer

Prontosan® Wound Irrigation Solution

Instructions for use for cleansing, rinsing and moistening of acute, chronic and infected skin wounds, 1st and 2nd degree burns

1. Introduction: Chronic skin wounds are often coated with slough, necrotic tissue and/or biofilm. These coatings are difficult to remove and lead to delayed wound healing. Prontosan® Wound Irrigation Solution is able to remove these barriers to wound healing through its cleansing activity.

Acute wounds also require proper cleansing as they are generally contaminated with debris and microorganisms. These contaminants can interfere with the normal wound healing process and lead to complications such as infection. Due to the unique combination of ingredients (i.e. the antimicrobial substance, polihexanide, and the surfactant, be-taine), Prontosan® is ideal for the prevention of biofilm formation.

2. Product profile and areas for use

For cleansing and irrigation plus moistening of:

- acute non-infected and infected wounds: - traumatic wounds (e.g. skin lacerations, bites, cuts or crush injuries); -postoperative wounds.
- chronic non-infected and infected wounds including: pressure sores; venous ulcers; diabetic ulcers.
- thermal and chemical wounds: 1st and 2nd degree burns; chemical burns.
- post-radiation wounds.
- fistulas and abscesses.
- entry ports of urological catheters, PEG/PEJ tubes or drainage tubes.
- peristomal skin.

For intraoperative cleansing and irrigation of wounds.

For instillation in combination with negative pressure wound therapy.

For moistening encrusted dressings and bandages prior to removal.

3. General use: Prontosan® Wound Irrigation Solution (see separate product information) should be used for wound cleansing prior to treatment with Prontosan® Wound Gel or Prontosan® Wound Gel X.

Prontosan® Wound Irrigation Solution may be used to saturate compresses, gauzes or pads for cleansing as needed.

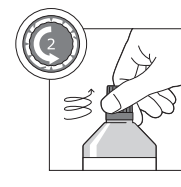
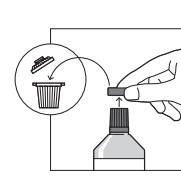
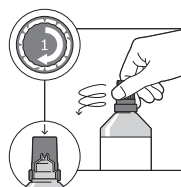
Application should be conducted frequently in order to achieve and maintain an visually clean wound.

Prontosan® Wound Irrigation Solution may be warmed to body temperature prior to use. Wound dressings and bandages are frequently encrusted and adhere to the wound surface. Removal of these dressings can traumatise the wound bed, which in turn delays wound healing. In cases where dressings and bandages are difficult to release due to encrustation, soaking the dressing with Prontosan® Wound Irrigation Solution is recommended until they can be gently removed.

4. Wound cleansing: The entire wound, as well as the surrounding area, should be thoroughly cleansed with Prontosan® Wound Irrigation Solution.

For non-severe and acute wounds rinsing is sufficient. For wounds covering a large area and also wounds difficult to access, soaking the affected area with Prontosan® Wound Irrigation Solution for at least 15 minutes with a saturated compress is recommended. The solution should be used undiluted

5. Tissue tolerability and biocompatibility: Dermatologically tested and evaluated as non-irritating and well-tolerated; painless; no inhibition of granulation or epithelialisation.



6. Side effects: In very rare cases, there may be a mild burning sensation after application of Prontosan®, but this usually dissipates after a few minutes. Prontosan® can cause allergic reactions such as itching (urticaria) and rashes (exanthema). In rare cases (less than 1 out of 10,000), anaphylactic shock has been reported.

7. Contraindications:

Prontosan® should not be used:

- if the patient is known to be allergic or if it is suspected that the patient may be allergic to one of the ingredients of the product.
- on the CNS or the meninges.
- in the middle or inner ear.
- in the eyes.
- on hyaline cartilage and in aseptic joint surgery. If Prontosan® does come into contact with aseptic cartilage, it should be immediately irrigated with Ringer's solution or normal saline.
- in combination with anionic tensides.
- in combination with cleansing soaps, ointments, oils, enzymes, etc. These substances should be thoroughly removed from the wound before use.
- for peritoneal lavage or rinsing.

8. Restrictions of use: Pregnancy and lactation period: There is no evidence of mutagenic or embryo toxicity associated with the ingredients of this product. As there is no systemic reabsorption of polihexanide, transmission to breast milk is unlikely. Due to the lack of relevant clinical trials and clinical experience with pregnant and breast feeding women, Prontosan® Wound Irrigation Solution should only be used after careful medical consultation in these cases.

Newborns and infants: Due to insufficient clinical data, Prontosan® Wound Irrigation Solution should only be used selectively and under close medical supervision in newborns and infants.

9. General safety instructions: For external use only. Do not use for infusion or injection. Do not swallow.

Do not use damaged bottles. Keep bottles away from direct sunlight. Keep out of reach of children.

10. Summary / technical information: Prontosan® Wound Irrigation Solution is a preserved product and has a shelf life of 8 weeks after opening. The bottle should be closed immediately after use to prevent contamination. The top of the bottle should be protected from contamination during use. Bottles that have come into direct contact with the wound or have become contaminated in another way must be discarded.

Composition: Purified Water, Betaine surfactant, 0.1 % Polyaminopropyl Biguanide (Polihexanide).

Appearance and smell: clear, colourless and virtually odourless, aqueous solution.

Shelf life: according to the expiry date (max. 36 month); store at room temperature.

Originality: sterile, originality seal.

Ampoules: for single use only.