Prontosan® Wound Gel X

Instructions for use for cleansing, moistening and decontamination of acute, chronic and infected dermal wounds and burn.

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. Therefore, proper wound cleansing is essential. The use of Prontosan® Wound Gel X provides long-lasting cleansing and decontamination of the wound bed between dressing changes.

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. For acute traumatic wounds that require suturing, Prontosan® Wound Gel X should be applied after surgical intervention and suturing.

Due to the unique combination of ingredients (i.e. the antimicrobial substance, polihexanide, and the surfactant, betaine), Prontosan® is ideal for the prevention of biofilm formation. Test results support the claim that Prontosan® Gel is an effective barrier to reduce microbial penetration through the dressing.

2. Product profile and areas of use:
For cleansing, moistening and decontamination of:

a) acute non-infected and infected wounds: traumatic wounds (such as lacerations, abrasions or stab wounds - if suturing is indicated Prontosan® Wound Gel X should be applied only after surgical intervention)
b) chronic non-infected and infected wounds (including complex, recalcitrant wounds, cavity wounds, difficult-to-access wounds.
c) postoperative wounds.
d) thermal, chemical and post-radiation therapy burns:
- Superficial (First-degree, I)
- Superficial partial thickness (Second degree, IIa)
- Deep partial thickness (Second degree, IIb)
- Full thickness (Third degree, III)

e) frostbites.

3. General use: For optimal results, Prontosan® Wound Irrigation Solution (see separate product information) should be used for cleansing the wound and the skin area around the wound prior to treatment with Prontosan® Wound Gel X.

Prontosan® Wound Gel X should be copiously applied to the wound bed. Cavities and pockets should be filled with Prontosan® Wound Gel. Dressings, gauzes, compresses or other absorbent wound fillers can be moistened with Prontosan® Wound Gel X before the dressing is applied.

Prontosan® Wound Gel X may remain on the wound until the next dressing change.

Depending on the frequency of dressing changes, varying amounts of Prontosan® Wound Gel X are applied. The surface of the wound should be kept continuously moist to ensure adequate cleansing and decontamination. Coatings are gently released and removed with the next dressing change. Application should be conducted frequently enough for all coatings and necroses to be readily removed and for optimal wound bed preparation.

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

5. 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 with Prontosan® products.

6. Contraindications:
Prontosan® should not be used:

a) 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.
b) on the CNS or the meninges.
c) in the middle or inner ear.
d) in the eyes.
e) 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.
f) in combination with anionic tensides.
g) in combination with cleansing soaps, ointments, oils, enzymes, etc. These substances should be thoroughly removed from the wound before use.

7. 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 Gel X should only be used after careful medical consultation in these cases.

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

8. General safety instructions: For external use only. Do not use for infusion or injection. Do not swallow. Do not use damaged tubes. Keep bottles away from direct sunlight. Keep out of reach of children.

9. Summary/technical information: Prontosan® Wound Gel X is a preserved product that provides a sustained antimicrobial barrier. The tube should be closed immediately after use to prevent contamination. The top of tube should be protected from contamination during use. Tubes that have come into direct contact with the wound or have become contaminated in another way should be discarded.

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

Tubes are for single patient use only. **Appearance and smell:** clear, colourless and virtually odourless, aqueous gel. **Shelf life:** according to the expiry date; store at room temperature. **Shelf life after first opening:** 8 weeks. **Originality seal:** The product is no longer sterile after first opening.


Single use only.


Read instruction for use.


Keep out of reach of children.


Use by: month and year

Catalog number

Batch number

Shelf life after opening: 8 weeks


Manufacturer

Heat-sterilized

87324 - 2015-12-21

B. Braun Medical AG
Seesatz 17
CH-6204 Sempach
Switzerland

B|BRAUN

Distributor address:
B. Braun Australia Pty Ltd
Level 5, 7-9 Irvine Place
Bella Vista NSW 2153
Australia