

Prontosan[®] Wound Irrigation Solution

For cleansing wounds.
Also may be used for moistening and lubricating wound dressings.

STERILE A

Aseptic filtration <1 CFU/mL, until the product is first opened.

NONPYROGENIC fluid and fluid path prior to removal of cap.



Expiration Date

LOT

Lot Number

REF

Reorder Number



See Instructions for Use.



For single patient use only.
Do not resterilize.

Not made with natural rubber latex or DEHP.

880256
P-7249-7
REV. 1/20
Rx only

Description:

Prontosan Wound Irrigation Solution cleanses the tissue surface, even when surfaces are difficult to access such as **deep wound cavities, fissures, and wound pockets**. Prontosan Wound Irrigation Solution is a clear, colorless, and virtually odorless aqueous wound cleanser with surfactants.

Ingredients:

Prontosan Wound Irrigation Solution contains: Purified Water, 0.1 % Undecylenamidopropyl Betaine, 0.1 % Polyaminopropyl Biguanide (Polyhexanide [PHMB]).

pH may be adjusted with Sodium Hydroxide

Indications:

Prontosan Wound

Irrigation Solution is intended for cleansing wounds and for moistening and lubricating absorbant wound dressings for the management of ulcers, burns, post-surgical wounds, and abrasions.

Prontosan Wound Irrigation Solution may be used:

- For cleansing non-infected and infected wounds.
- For cleansing chronic skin wounds.
- For moistening encrusted bandages and wound dressings prior to removing.
- During dressing changes to loosen encrusted bandaging or other encrusted wound dressings.

Adverse Reactions:

In very rare cases there may be a mild burning

sensation after application which subsides after a few minutes. Prontosan Wound Irrigation Solution can cause allergic reactions such as itching and rashes. In rare cases (less than 1 out of 10,000), anaphylactic shock has been reported.

Contraindications:

- Prontosan Wound Irrigation Solution should not be used if there is a history of allergy to any of the ingredients.
- Do not use in the presence of hyaline cartilage.
- Do not use in combination with anionic tensides as these may impair preservation.
- Mixing Prontosan Wound Irrigation Solution with other

wound cleansing soaps, lotions, ointments, oils, or enzymes may lower efficacy. When such substances need to be removed from a wound, ensure the entire wound area is thoroughly rinsed with Prontosan Wound Irrigation Solution.

Warning:

Do not infuse, inject, or ingest. For external use only.

Storage Conditions:

Store at room temperature. Avoid excessive heat. Do not refrigerate or freeze.

Shelf-life:

Use prior to expiration date noted on the package label.

Instructions For Use

For General Use:

Cleanse the wounds with Prontosan Wound Irrigation Solution before further treatment is carried out.

When required, wash and decontaminate the whole section of the body or the whole body of the person affected according to institutional protocol.

Bandages or dressings soaked in Prontosan Wound Irrigation Solution can be used for cleaning as required.

Cleansing the Wound Site:

Cleansing of a large area around the whole wound site with Prontosan Wound Irrigation Solution is recommended.

For acute wounds rinsing

may be sufficient. For wounds covering a large area and wounds difficult to access, bathe the whole section of the body with Prontosan Wound Irrigation Solution, for at least 15 minutes. The solution should be used in an undiluted form.

For Use In the Case of Encrusted Bandages or when Changing Dressings Is Problematic:

In cases where bandages are difficult to release, wetting the wound dressing with Prontosan Wound Irrigation Solution is advisable until the bandages can be gently released without traumatizing the surface of the wound. If stubborn, large encrustations are present, the whole section of the body with the dressing can be saturated or bathed in Prontosan Wound Irrigation Solution until the dressing can be easily released.

Directions: Use Aseptic Technique.

1. To open container, firmly grasp tab between thumb and forefinger. Twist until tab separates from container.
2. Proceed with use as required in accordance with institutional protocol.
3. Discard any unused solution and container.

Antimicrobial Effectiveness Testing

Successfully meets USP<51> Category 2 Criteria

Preservative Testing

No microbial growth was observed at 7, 14 and 28 days for the following organisms:

Acinetobacter baumannii

Enterobacter cloacae

Enterococcus faecalis

Vancomycin Resistant *Enterococcus faecalis* (VRE)

Escherichia coli

Proteus mirabilis

Pseudomonas aeruginosa

Serratia marcescans

Staphylococcus aureus

Methicillin Resistant *Staphylococcus aureus* (MRSA)

Staphylococcus epidermidis

Candida albicans

Preservative testing demonstrated using USP<51>, with an expanded list of organisms and additional 7 day time-point, to support the role of PHMB as a preservative to inhibit microbial growth within the product during shelf storage.

Manufactured for:
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