

Prontosan[®] Wound Irrigation Solution

For cleaning wounds, and for moistening and lubricating absorbent wound dressings

STERILE by aseptic filtration <1 CFU/mL, until the product is first opened.

NONPYROGENIC fluid and fluid path prior to removal of cap.



Expiration Date



Lot Number



Reorder Number

Rx only

Not made with natural rubber latex or DEHP.

Pictorials are for reference only.



For single patient use only. Do not resterilize.



See Instructions for Use.

880287 P-7579-6 REV. 11/16



Description:

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

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 cleaning wounds and for moistening and lubricating absorbent wound dressings for the management of ulcers, burns, post-surgical wounds and abrasions.

Prontosan Wound Irrigation Solution may be used:

- For cleansing and moistening chronic skin wounds
- For moistening of bandages and wound dressings, such as compresses, gauze, pads,

sponges, gels, hydrofibres, alginates, hydrocolloids, etc.

- 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 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 tensesides 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.

Warnings:

- For external use only on skin wounds.
- Do not use for infusion or injection.
- Do not ingest.

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. Although no longer sterile once the bottle has been opened, because of preservative, there is a shelf-life of 28 days after opening the bottle as long as it is closed immediately after use and the top of the bottle is protected from contamination or direct contact.

Bottles that become contaminated or have come into direct contact with the wound must be discarded.

Instructions For Use

For General Use:

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

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.

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

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. Remove cap.
2. Remove and discard white ring below cap.
3. Replace cap. Ensure cap is screwed down fully to pierce container.
4. Remove cap and proceed with use as required in accordance with institutional protocol.
5. Replace cap after use in accordance with institutional protocol.
6. Record date opened on bottle.
7. Solution may be used for up to 28 days.
8. Discard any unused solution and bottle.

Antimicrobial Effectiveness Testing

Successfully meets USP<51> Category 2 Criteria

Organisms	Result Day 14	Result Day 28
<i>Escherichia coli</i> (ATCC 8739)	Greater than 2.0 log reduction from the initial count.	No increase from the 14 days count.
<i>Pseudomonas aeruginosa</i> (ATCC 9027)		
<i>Staphylococcus aureus</i> (ATCC 6538)		
<i>Candida albicans</i> (ATCC 10231)	No increase from the initial calculated count.	No increase from the initial calculated count.
<i>Aspergillus niger</i> (ATCC 16404)		

Preservative Testing¹

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

¹ Preservative effectiveness 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.

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