Prontosan® Wound Gel

For removal of wound coatings, cleaning of 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.

Single patient use solution in multiple use container. Do not resterilize.

See instructions for use.

Rx only

Expiration Date

LOT Lot Number

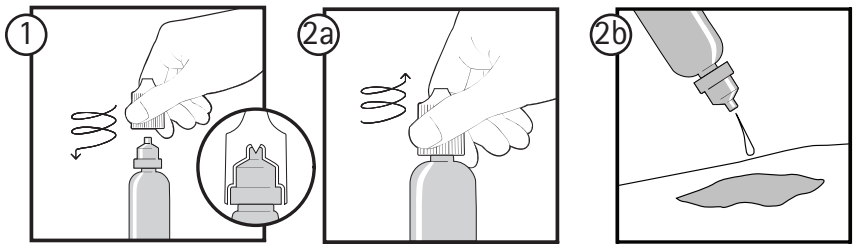
REF Reorder Number

Not made with natural rubber latex or DEHP.

Pictorials are for reference only.

880318 P-7616-3 REV. 11/15

30 mL



Description:

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

Summary / technical information:

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

PHMB at a concentration of 0.1% w/w is added to the product as a preservative to inhibit the growth of microorganisms within the product.

Indications:

Prontosan Wound Gel is intended to cleanse and moisten wound beds and for the management of ulcers, first and second degree burns, cuts, partial and full thickness wounds, and surgical incisions. It can be used during wound dressing changes to soften encrusted wound dressings.

Prontosan Wound Gel may be used:

- For cleansing wounds or wound coatings
- For cleansing and moistening chronic skin wounds
- For moistening of bandages and wound dressings, such as compresses, gauze, pads, sponges, 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 Gel 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 Gel 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 a cleansing solution such as 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. Protect from freezing.

Preservation and 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.

Instructions For Use

For general use:

Rinsing and cleansing the wound and surrounding area is recommended prior to application of Prontosan Wound Gel. Prontosan Wound Irrigation Solution can be used for this purpose. Refer to cleansing solution instructions for use.

Apply a 3-5 mm coating of Prontosan Wound Gel directly to shallow flat wound surfaces or deep wound fissures. Bandages or dressings soaked in Prontosan Wound Gel can be used for cleaning as required.

Prontosan Wound Gel can be used to sustain wound moisture for the duration of time between dressing changes per institutional protocol.

Directions: Use Aseptic Technique.

1. To open, screw cap down fully to pierce container.
2. Remove cap and proceed with use as required in accordance with institutional protocol.
3. Replace cap after use in accordance with institutional protocol.

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