Prontosan® Wound Irrigation Solution

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

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
See Instructions for Use.

Rx only
Not made with natural rubber latex or DEHP.
Potentials are for reference only.

\[880287\  P-7579-7\  REV.5/17\]

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, gaze, pads, sponges, gels, hydrofibres, alginites, hydrocolloids, etc.

Contraindications:
Prontosan Wound Irrigation Solution should not be used if there is a history of allergy to any of the ingredients.

Adverse Reactions:
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.

Results of Antimicrobial Effectiveness Testing

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

Preservative Effectiveness Testing

No microbial growth was observed at 7, 14 and 28 days for the following organisms:
- Acinetobacter baumanii
- Enterobacter cloacae
- Enterococcus faecalis
- Vancomycin Resistant Enterococcus faecalis (VRE)
- Escherichia coli
- Proteus mirabilis
- Pseudomonas aeruginosa
- Seratia 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.

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.

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.

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.

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

M manufactured for:
B. Braun Medical Inc.
Bethlehem, PA 18018-3524 USA
1-800-227-2862