

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.

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

pH may be adjusted with Sodium Hydroxide

Application: Rinse wound thoroughly with Prontosan solution. For thickly encrusted wounds: allow solution to soak in for 15 minutes. No rinsing required afterwards. Dressings and scabs sticking to wounds can be removed by soaking with Prontosan solution.

For external use on skin wounds only.

Do not use for infusion or injection.

Do not ingest.

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

Use this product within 28 days after opening.

Date Opened:

Close bottle immediately after use.

Prontosan®

Wound Irrigation Solution



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



LOT

REF XXXXXX

GTIN XXXXXXXXXXXXX

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

NONPYROGENIC fluid and fluid path prior to removal of cap.



For single patient use only. Do not resterilize.

Rx only



See Instructions for Use.

Not made with natural rubber latex or DEHP.

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Manufactured for:
B. Braun Medical Inc.
Bethlehem, PA 18018-3524 USA
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www.prontosan.bbbrainusa.com
Made in Germany.

350 mL

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REV. 11/16