

# Prontosan<sup>®</sup> Wound Gel X

For maintaining a clean and moist wound environment that is conducive to healing

STERILE by steam sterilization, until the product is first opened.  
NONPYROGENIC  
fluid and fluid path prior to removal of cap.



For single patient use only.  
Do not resterilize.



See instructions for use.

Rx only



Expiration Date



Lot Number



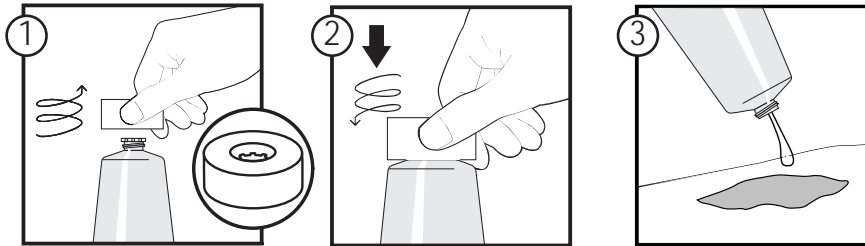
Reorder Number

Not made with natural rubber latex or DEHP.

Pictorials are for reference only.

87316

P-8265-2 REV. 9/17



## Description:

Prontosan Wound Gel X is a clear, colorless, and virtually odorless aqueous amorphous hydrogel wound dressing.

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

PHMB is added to the product as a preservative to inhibit the growth of microorganisms within the product.

## Indications:

Prontosan Wound Gel X is indicated for the management of ulcers (including diabetic foot and leg ulcers and pressure ulcers), first and second degree burns, partial and full thickness wounds, large surface area wounds, and surgical incisions.

Prontosan Wound Gel X

- is an effective microbial barrier
- resists microbial colonization within the dressing
- reduces microbial penetration through the dressing
- softens necrotic tissue facilitating autolytic debridement

## 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 with Prontosan products.

## Contraindications:

- Prontosan Wound Gel X 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 surfactants as these may impair preservation.
- Mixing Prontosan Wound Gel X with other wound cleansing soaps, lotions, ointments, oils, or enzymes may lower efficacy.
- Do not use in the middle or inner ear.
- Do not use in the eyes.

## Warnings:

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

## Storage Conditions:

Store at room temperature. 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 tube has been opened, because of

preservative, there is a shelf-life of 8 weeks after first opening the tube. Close immediately after use and protect the top of the tube 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 X. Prontosan Wound Irrigation Solution can be used for this purpose. Refer to cleansing solution instructions for use.

Apply a generous amount of Prontosan Wound Gel X directly to the wound.

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

## Directions: Use Aseptic Technique.

1. Remove cap from tube.
2. Invert screw cap and press keyed indent on cap top onto keyed sealed tube. Ensure cap is firmly seated. Rotate cap to open the seal on the tube.
3. Proceed with use as required in accordance with institutional protocol.
4. Replace cap after use in accordance with institutional protocol.

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

**B | BRAUN**

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REVISIONS				
INIT.	REV.	ZONE	DESCRIPTION	DATE
KW	1	N/A	INITIATED PER PFG 2014-76 REV 0; DWG-MD-2023212	12.4.2014
KW	2	N/A	1605007; TO ESTABLISH A 1 OZ. PRONTOSAN GEL X PRODUCT CODE; REMOVED CONTAINER SIZE & WEBSITES	10.10.2017

D

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C

C

SIZE: 8.25 X 11.7 (APPROX.)

MATERIAL: WHITE PAPER

PRINT: BLACK

NOTE: SEE ATTACHED SHEET FOR ARTWORK

B

B

A

A

DRAWN	KW	12.4.2014	<b>B   BRAUN</b> B. Braun Medical Inc. Bethlehem, PA 18018
CHECKED			
ENG APPR.			
QA APPR.			PRODUCT CODE: N/A
	INITIAL	DATE	TITLE: INSTRUCTION SHEET (PFG); PRONTOSAN WOUND GEL X; B. BRAUN SWITZERLAND
UNLESS OTHERWISE SPECIFIED: DIMENSIONS ARE IN INCHES TOLERANCES: FRACTIONAL: ±1/16 ANGULAR: ±1/2° TWO PLACE DECIMAL: ±.06 THREE PLACE DECIMAL: ±.062			SIZE: <b>A</b>
			DWG. NO.: <b>P-8265(s)</b>
			REV: <b>2</b>
			SCALE: 1:1
			SHEETS: 1 OF 1
CAUTION: This drawing is the property of B. Braun Medical Inc. Information hereon is CONFIDENTIAL. Unauthorized use is prohibited.			

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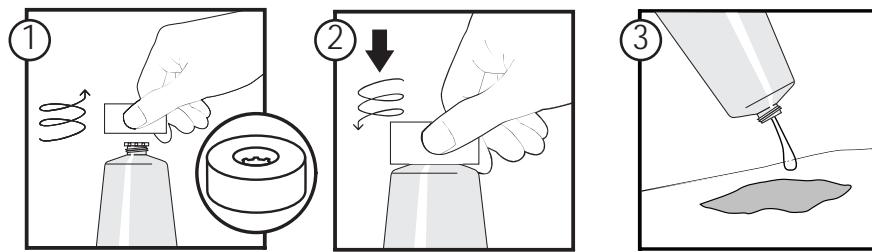
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## Warnings:

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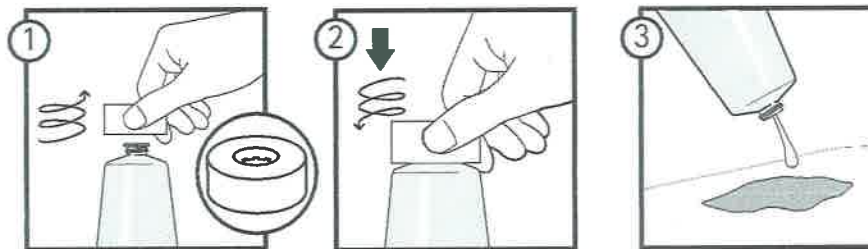
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LABELING APPROVAL  
INITIALS KW  
DATE 10.31.17