

For removal of wound coatings, cleaning of wounds, and for moistening and lubricating absorbent wound dressings.

## Description:

Prontosan Wound Gel is a clear, colorless, and virtually odorless gel used to clean the wound surface, even those that are difficult to access.

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

For single patient use only.

Not made with natural rubber latex or DEHP.

## Ingredients:

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 growth of microorganisms within the product.

## Indications:

Prontosan Wound Gel is intended to cleanse and moisten the wound bed and for the management of minor cuts, abrasions, lacerations and minor

burns. It can be used during wound dressing changes to soften 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.

## Warnings:

- Do not use if you have an allergy to one or more of the ingredients.
- Do not use on exposed cartilage.
- Do not use or mix with other cleansers, soaps, lotions, or ointments.
- For external use only on skin wounds.
- Do not use for infusion or injection.
- Do not swallow.
- Do not use in the eye.

## Storage Conditions:

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

## Shelf-life:

28 days after opening as long as cap is replaced immediately after each use.

Use prior to expiration date.

## Instructions For Use

Use only as directed.

### For general use:

Rinsing and cleaning 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 cleaning solution instructions for use.

Apply an even coating of Prontosan Wound Gel directly to entire wound.

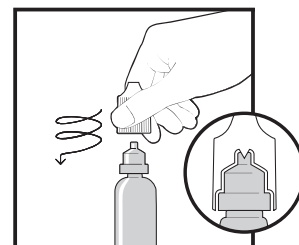
Bandages or dressings soaked in Prontosan Wound Gel can be used for cleaning as required.

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

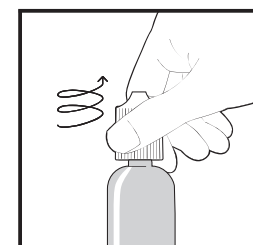
Pictorials are for reference only.

**Directions:** Wash hands before use, and avoid contact with container opening and inside of cap.

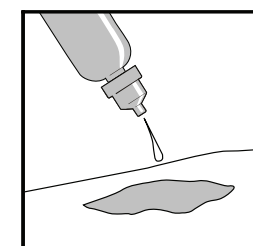
1. To open, screw cap down fully to pierce container.



2. Remove cap.



3. Proceed with use.



4. Replace cap after use.

REVISIONS				
INIT.	REV.	ZONE	DESCRIPTION	DATE
KAH	1	N/A	INITIATED PER PFG 2011-02; DWG-MD-2020184	3.17.2011
MS	2	N/A	PFG 2014-90 REV 0; UDI COMPLIANT PER SOP-MD-2018771	11.12.2015

# Prontosan<sup>®</sup> Wound Gel

30 mL

For removal of wound coatings, cleaning of wounds, and for moistening and lubricating absorbent wound dressings.

880419 P-7916-2  
REV. 11/15

### Description:

Prontosan Wound Gel is a clear, colorless, and virtually odorless gel used to clean the wound surface, even those that are difficult to access.

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

For single patient use only.

Not made with natural rubber latex or DEHP.

### Ingredients:

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 growth of microorganisms within the product.

### Indications:

Prontosan Wound Gel is intended to cleanse and moisten the wound bed and for the management of minor cuts, abrasions, lacerations and minor

burns. It can be used during wound dressing changes to soften 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.

### Warnings:

- Do not use if you have an allergy to one or more of the ingredients.
- Do not use on exposed cartilage.
- Do not use or mix with other cleansers, soaps, lotions, or ointments.
- For external use only on skin wounds.
- Do not use for infusion or injection.
- Do not swallow.
- Do not use in the eye.

### Storage Conditions:

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

### Shelf-life:

28 days after opening as long as cap is replaced immediately after each use.

Use prior to expiration date.

### Instructions For Use

Use only as directed.

### For general use:

Rinsing and cleaning 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 cleaning solution instructions for use.

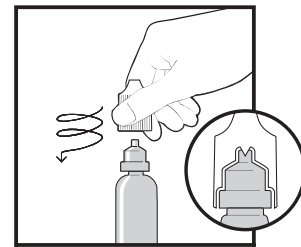
Apply an even coating of Prontosan Wound Gel directly to entire wound. Bandages or dressings soaked in Prontosan Wound Gel can be used for cleaning as required.

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

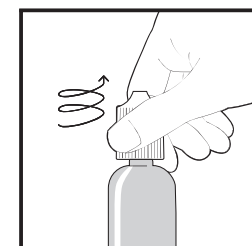
Pictorials are for reference only.

**Directions:** Wash hands before use, and avoid contact with container opening and inside of cap.

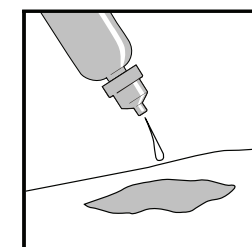
1. To open, screw cap down fully to pierce container.



2. Remove cap.



3. Proceed with use.



4. Replace cap after use.

**B | BRAUN**

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

SIZE: 210 mm X 297 mm (APPROX.)

MATERIAL: WHITE PAPER

PRINT: BLACK

DRAWN	KAH	3.17.2011	<b>B   BRAUN</b> B. Braun Medical Inc. Bethlehem, PA 18018
CHECKED			
ENG APPR.			
QA APPR.			
	INITIAL	DATE	PRODUCT CODE: 400561
UNLESS OTHERWISE SPECIFIED: DIMENSIONS ARE IN INCHES TOLERANCES: FRACTIONAL: ±1/16 ANGULAR: ±1/2° TWO PLACE DECIMAL: ±.06 THREE PLACE DECIMAL: ±.062			TITLE: INSTRUCTION SHEET (PFG); PRONTOSAN WOUND GEL OTC 30 mL B. BRAUN SEMPACH
	SIZE:	DWG. NO.:	REV:
	C	P-7916	2
	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.			

# Prontosan<sup>®</sup> Wound Gel

30 mL

For removal of wound coatings, cleaning of wounds, and for moistening and lubricating absorbent wound dressings.

8800419 P-7916-2  
REV. 11/15

## Description:

Prontosan Wound Gel is a clear, colorless, and virtually odorless gel used to clean the wound surface, even those that are difficult to access.

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

For single patient use only.

Not made with natural rubber latex or DEHP.

## Ingredients:

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 growth of microorganisms within the product.

## Indications:

Prontosan Wound Gel is intended to cleanse and moisten the wound bed and for the management of minor cuts, abrasions, lacerations and minor

burns. It can be used during wound dressing changes to soften 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.

## Warnings:

- Do not use if you have an allergy to one or more of the ingredients.
- Do not use on exposed cartilage.
- Do not use or mix with other cleansers, soaps, lotions, or ointments.
- For external use only on skin wounds.
- Do not use for infusion or injection.
- Do not swallow.
- Do not use in the eye.

## Storage Conditions:

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

## Shelf-life:

28 days after opening as long as cap is replaced immediately after each use.

Use prior to expiration date.

## Instructions For Use

Use only as directed.

### For general use:

Rinsing and cleaning 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 cleaning solution instructions for use.

Apply an even coating of Prontosan Wound Gel directly to entire wound.

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.

Pictorials are for reference only.

**Directions:** Wash hands before use, and avoid contact with container opening and inside of cap.

1. To open, screw cap down fully to pierce container.



2. Remove cap.



3. Proceed with use.



4. Replace cap after use.

# B | BRAUN

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

LABELING APPROVAL	
INITIALS	<u>MS</u>
DATE	<u>1-20-16</u>

LABELING APPROVAL	
INITIALS	<u>AP</u>
DATE	<u>1-21-16</u>