

Prontosan[®] Wound Irrigation Solution 350 mL

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

880423 P-7914-3
REV. 11/15

Description:

Prontosan Wound Irrigation Solution is a clear, colorless, and nearly odorless waterbased solution used to clean wound surfaces, 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:

Purified Water,
0.1% Undecylenamidopropyl Betaine,
0.1% Polyaminopropyl Biguanide (Polyhexanide [PHMB]),
pH may be adjusted with Sodium Hydroxide.

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 Irrigation Solution is intended to clean wounds and moisten absorbent wound dressings and for the management of minor cuts, abrasions, lacerations and minor burns.

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 by IV 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 and the top of the bottle is protected from contamination.

Bottles that become contaminated or have come into direct contact with the wound must be discarded. Use prior to expiration date.

Instructions For Use:

Use only as directed.

Do not dilute the solution before use.

Cleaning the Wound Site:

Clean the wound and surrounding area with Prontosan Wound Irrigation Solution before further treatment is carried out.

For wounds covering a large area and wounds difficult to access, bathe the whole

section of the body with Prontosan Wound Irrigation Solution.

Bandages or dressings soaked in Prontosan Wound Irrigation Solution can be used for cleaning by applying saturated bandage directly on the wound.

- Rinse wound thoroughly with Prontosan Solution. For thickly encrusted wounds, allow solution to soak in until scab is softened.
- Prontosan Solution can be used to irrigate wound by squeezing directly from container. No rinsing is required afterwards.
- Reapply Prontosan Solution with each dressing change.
- Prontosan Gel can be used to keep the wound moist prior to applying the dressing. Refer to Prontosan Gel Instructions for Use.

For Use In the Case of Encrusted Bandages or when Changing Dressings Is Problematic:

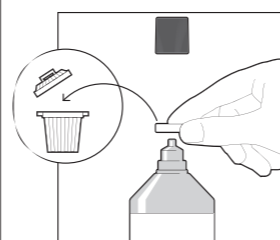
Saturate the wound dressing with Prontosan Wound Irrigation Solution until the bandages can be gently released without damaging the surface of the wound.

Directions: Wash hands before use and avoid contact with the bottle rim, inside of cap or solution.

1. Remove cap.



2. Remove and discard white ring below cap.



Continued on back.

Continued from front.

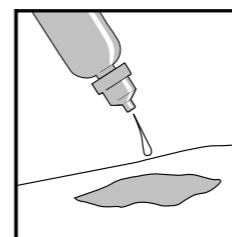
3. Replace cap. Ensure cap is screwed down fully to pierce container.



4. Remove cap.



5. Proceed with use.



6. Replace cap

7. Record date opened on bottle.

8. Solution may be used for up to 28 days after opening.

9. Discard any unused solution and bottle after 28 days.

Pictorials are for reference only.

B | BRAUN

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

REVISIONS				
INIT.	REV.	ZONE	DESCRIPTION	DATE
KAH	1	N/A	INITIATED PER PFG 2011-03 R0; DWG-MD-2020423	6.8.2011
KW	2	N/A	PFG 2014-67 REV 0; UPDATED INSTRUCTIONS	10.28.2014
MS	3	N/A	PFG 2014-90 REV 0; UDI COMPLIANT PER SOP-MD-2018771	11.12.2015

Prontosan[®] Wound Irrigation Solution 350 mL

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

880423 P-7914-3
REV. 11/15

Description:

Prontosan Wound Irrigation Solution is a clear, colorless, and nearly odorless waterbased solution used to clean wound surfaces, 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:

Purified Water,
0.1% Undecylenamidopropyl Betaine,
0.1% Polyaminopropyl Biguanide (Polyhexanide [PHMB]),
pH may be adjusted with Sodium Hydroxide.

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 Irrigation Solution is intended to clean wounds and moisten absorbent wound dressings and for the management of minor cuts, abrasions, lacerations and minor burns.

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 by IV 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 and the top of the bottle is protected from contamination.

Bottles that become contaminated or have come into direct contact with the wound must be discarded. Use prior to expiration date.

Instructions For Use:

Use only as directed. Do not dilute the solution before use.

Cleaning the Wound Site:

Clean the wound and surrounding area with Prontosan Wound Irrigation Solution before further treatment is carried out.

For wounds covering a large area and wounds difficult to access, bathe the whole

section of the body with Prontosan Wound Irrigation Solution.

Bandages or dressings soaked in Prontosan Wound Irrigation Solution can be used for cleaning by applying saturated bandage directly on the wound.

- Rinse wound thoroughly with Prontosan Solution. For thickly encrusted wounds, allow solution to soak in until scab is softened.

- Prontosan Solution can be used to irrigate wound by squeezing directly from container. No rinsing is required afterwards.

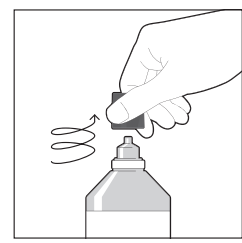
- Reapply Prontosan Solution with each dressing change.
- Prontosan Gel can be used to keep the wound moist prior to applying the dressing. Refer to Prontosan Gel Instructions for Use.

For Use In the Case of Encrusted Bandages or when Changing Dressings Is Problematic:

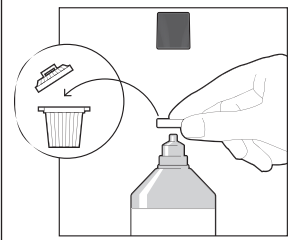
Saturate the wound dressing with Prontosan Wound Irrigation Solution until the bandages can be gently released without damaging the surface of the wound.

Directions: Wash hands before use and avoid contact with the bottle rim, inside of cap or solution.

1. Remove cap.



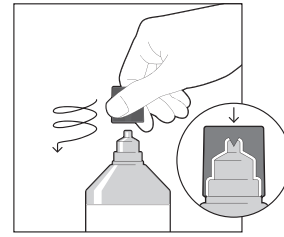
2. Remove and discard white ring below cap.



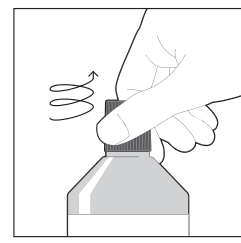
Continued on back.

Continued from front.

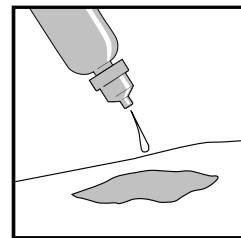
3. Replace cap. Ensure cap is screwed down fully to pierce container.



4. Remove cap.



5. Proceed with use.



6. Replace cap

7. Record date opened on bottle.

8. Solution may be used for up to 28 days after opening.

9. Discard any unused solution and bottle after 28 days.

Pictorials are for reference only.

B | BRAUN

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

FRONT

BACK

SIZE: 21 cm x 29-3/4 cm (APPROX.)

MATERIAL: WHITE OPAQUE PAPER

PRINT: BLACK

DRAWN	KAH	6.8.2011	B BRAUN B. Braun Medical Inc. Bethlehem, PA 18018
CHECKED			
ENG APPR.			
QA APPR.			
	INITIAL	DATE	PRODUCT CODE: 400444
UNLESS OTHERWISE SPECIFIED: DIMENSIONS ARE IN INCHES TOLERANCES: FRACTIONAL: ±1/4 ANGULAR: ±1/2° TWO PLACE DECIMAL: ±.25 THREE PLACE DECIMAL: ±.250			TITLE: INSTRUCTION SHEET (PFG); PRONTOSAN WOUND IRRIGATION SOLUTION 350 ML OTC B. BRAUN SWITZERLAND/SEMPACH
SIZE:	DWG. NO.:	REV:	
C	P-7914	3	
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[®] Wound Irrigation Solution 350 mL

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

880423 P-7914-3
REV. 11/15

Description:

Prontosan Wound Irrigation Solution is a clear, colorless, and nearly odorless waterbased solution used to clean wound surfaces, 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:

Purified Water,
0.1% Undecylenamidopropyl Betaine,
0.1% Polyaminopropyl Biguanide (Polyhexanide [PHMB]),
pH may be adjusted with Sodium Hydroxide.

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 Irrigation Solution is intended to clean wounds and moisten absorbent wound dressings and for the management of minor cuts, abrasions, lacerations and minor burns.

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 by IV 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 and the top of the bottle is protected from contamination.

Bottles that become contaminated or have come into direct contact with the wound must be discarded. Use prior to expiration date.

Instructions For Use:

Use only as directed. Do not dilute the solution before use.

Cleaning the Wound Site:

Clean the wound and surrounding area with Prontosan Wound Irrigation Solution before further treatment is carried out.

For wounds covering a large area and wounds difficult to access, bathe the whole

section of the body with Prontosan Wound Irrigation Solution.

Bandages or dressings soaked in Prontosan Wound Irrigation Solution can be used for cleaning by applying saturated bandage directly on the wound.

- Rinse wound thoroughly with Prontosan Solution. For thickly encrusted wounds, allow solution to soak in until scab is softened.
- Prontosan Solution can be used to irrigate wound by squeezing directly from container. No rinsing is required afterwards.
- Reapply Prontosan Solution with each dressing change.
- Prontosan Gel can be used to keep the wound moist prior to applying the dressing. Refer to Prontosan Gel Instructions for Use.

For Use In the Case of Encrusted Bandages or when Changing Dressings Is Problematic:

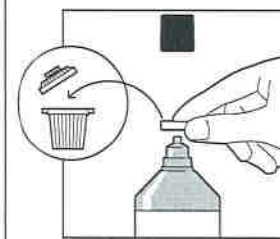
Saturate the wound dressing with Prontosan Wound Irrigation Solution until the bandages can be gently released without damaging the surface of the wound.

Directions: Wash hands before use and avoid contact with the bottle rim, inside of cap or solution.

1. Remove cap.



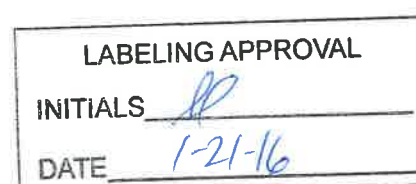
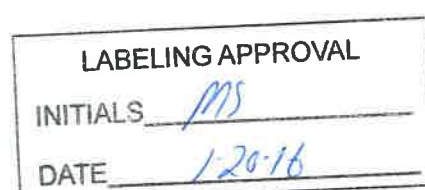
2. Remove and discard white ring below cap.



Continued on back.

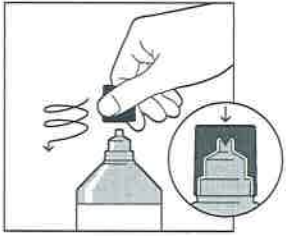
B | BRAUN

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



Continued from front.

3. Replace cap. Ensure cap is screwed down fully to pierce container.



4. Remove cap.



5. Proceed with use.



6. Replace cap
7. Record date opened on bottle.
8. Solution may be used for up to 28 days after opening.
9. Discard any unused solution and bottle after 28 days.

Pictorials are for reference only.

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

LABELING APPROVAL	
INITIALS	<u>ll</u>
DATE	<u>4-4-16</u>