

PURPREP- povidone iodine and isopropyl alcohol sponge
CareFusion 213 LLC

PurPrep

Isopropyl alcohol 72.5% w/w

Povidone-iodine 8.3% w/w (0.83% available iodine)

Antiseptic

Antiseptic

for the preparation of the patient's skin prior to surgery. Helps to reduce bacteria that potentially can cause skin infection.

For external use only. Flammable, keep away from fire or flame.

To reduce risk of fire, PREP CAREFULLY:

- do not use 26-mL applicator for head and neck surgery
- solution contains alcohol and gives off **flammable vapors**.
- avoid getting solution into hairy areas. Hair may take up to 1 hour to dry. **Wet hair is flammable**.
- do not drape or use ignition source (e.g., cautery, laser) until solution is completely dry (**minimum of 3 minutes on hairless skin; up to 1 hour in hair**)
- do not allow the solution to pool
- remove wet materials from prep area

Do not use

- on children less than 2 months of age because of the potential for excessive skin irritation and increased drug absorption. Daily use of iodine on newborn infants may increase blood iodine level.
- on open skin wounds or as a general skin cleanser
- in the eyes or for prepping mucous membranes
- on iodine sensitive patients

When using this product

- use in well ventilated area.
- use with caution in women who are breast-feeding due to the potential for transient hypothyroidism in the nursing newborn

Stop use and ask a doctor if irritation, sensitization, or allergic reaction occurs. These may be signs of a serious condition.

Keep out of the reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

Directions

- ◦ use in a well ventilated area
- ◦ do not allow solution to pool; tuck prep towels to absorb solution, and then remove
- ◦ remove applicator from package; do not touch sponge

- hold the applicator with the sponge down. Pinch wings **only once** to activate the ampules and release the antiseptic.
 - wet the sponge by pressing and releasing the sponge against the treatment area until liquid is visible on the skin
 - completely wet the treatment area with antiseptic
 - **dry surgical sites** (e.g., abdomen or arm): use repeated back-and-forth strokes for 30 seconds
 - **moist surgical sites** (e.g., inguinal fold): use repeated back-and-forth strokes for 2 minutes
 - **allow the solution to completely dry (minimum of 3 minutes on hairless skin; up to 1 hour in hair).** Do not blot or wipe away.
 - discard prepping materials, including solution soaked materials. It is not necessary to use the entire amount available
- store between 15-30 ° C (59-86 ° F)
 - avoid excessive heat above 40 ° C (104 ° F)

Acrylates Copolymer, Acrylates/Octylacrylamide Copolymer, Aminomethyl Propanol, Polyethylene Glycol, USP Purified Water

Questions? call **1-800-523-0502** (M-F 8 a.m.-5 p.m. CST)



BD PurPrep™

26 mL Applicator

NDC 54365-014-42
REF 960120

Povidone-Iodine 8.3% w/w (0.83% available iodine) with isopropyl alcohol 72.5% w/w

Patient Preoperative Skin Preparation

Sterile Solution

Applicator is sterile if package is intact



STERILE SOLUTION



STERILE EO





LATEX



External Use Only
Professional Use Only

⚠ WARNING • FLAMMABLE



Keep away from fire or flame.

To reduce risk of fire, PREP CAREFULLY:

- do not use 26-mL applicator for head and neck surgery
- solution contains alcohol and gives off **flammable vapors**
- avoid getting solution into hairy areas. Hair may take up to 1 hour to dry. **Wet hair is flammable.**
- do not drape or use ignition source (e.g., cautery, laser) until solution is completely dry (**minimum of 3 minutes on hairless skin; up to 1 hour in hair**)
- do not allow solution to pool
- remove wet materials from prep area

Drug Facts

Active Ingredients

Purposes

Active ingredients

Isopropyl Alcohol 72.5% w/w Antiseptic
Povidone-iodine 8.3% w/w (0.83% available iodine) Antiseptic

Purposes

Use for the preparation of the patient's skin prior to surgery. Helps to reduce bacteria that potentially can cause skin infection.

Warnings

For external use only. Flammable, keep away from fire or flame.

To reduce risk of fire, PREP CAREFULLY:

- do not use 26-ml applicator for head and neck surgery
- solution contains alcohol and gives off **flammable vapors**
- avoid getting solution into hairy areas. Hair may take up to 1 hour to dry. **Wet hair is flammable.**
- do not drape or use ignition source (e.g., cautery, laser) until solution is completely dry (minimum of 3 minutes on hairless skin; up to 1 hour in hair)
- do not allow solution to pool
- remove wet materials from prep area

Do not use • on children less than 2 months of age because of the potential for excessive skin irritation and increased drug absorption. Daily use of iodine on newborn infants may increase blood iodine level. • on open skin wounds or as a general skin cleanser • in the eyes or for prepping mucous membranes • on iodine sensitive patients

When using this product

- use in well ventilated area
- use with caution in women who are breast-feeding due to the potential for transient hypothyroidism in the nursing newborn

Stop use and ask a doctor if irritation, sensitization, or allergic reaction occurs. These may be signs of a serious condition.

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

Directions

- use in a well ventilated area
- do not allow solution to pool; tuck prep towels to absorb solution, and then remove
- remove applicator from package; do not touch sponge
- hold the applicator with the sponge down. Pinch wing **only once** to activate the ampules and release the antiseptic.
- wet the sponge by pressing and releasing the sponge against the treatment area until liquid is visible on the skin
- completely wet the treatment area with antiseptic
- **dry surgical sites** (e.g., abdomen or arm): use repeated back-and-forth strokes for 30 seconds
- **moist surgical sites** (e.g., inguinal fold): use repeated back-and-forth strokes for 2 minutes
- **allow the solution to completely dry (minimum of 3 minutes on hairless skin; up to 1 hour in hair).** Do not blot or wipe away.
- discard prepping materials, including solution soaked materials. It is not necessary to use the entire amount available

Other information

- store between 15–30 °C (59–86 °F)
- avoid excessive heat above 40° C (104°F)

Inactive ingredient Acrylates Copolymer, Acrylates/
Octylacrylamide Copolymer, Aminomethyl Propanol, Polyethylene Glycol, USP
Purified Water

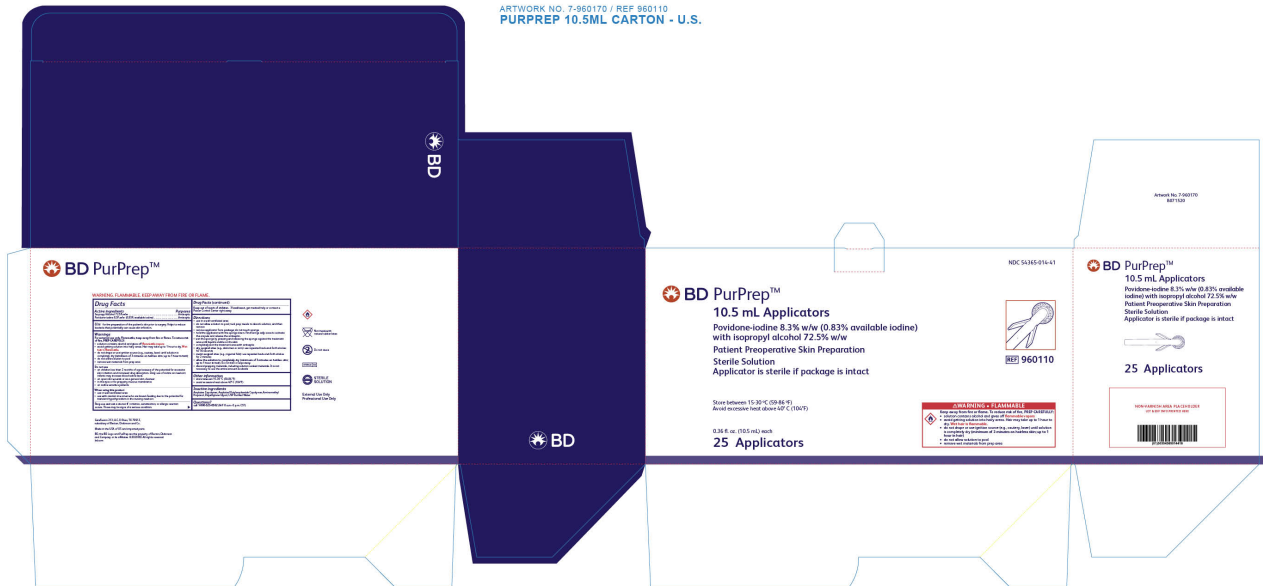
Questions? call 1-800-523-0502 (M-F 8 a.m.–5 p.m. CST)

CareFusion 213 LLC, El Paso, TX 79912, subsidiary of Becton,
Dickinson and Co. • Artwork No. 7-960140 • B071520 • Made in
the USA of US and imported parts • bd.com



(01)00354365014425

ARTWORK NO. 7-960170 / REF 960110
PURPREP 10.5ML CARTON - U.S.



PURPREP

povidone iodine and isopropyl alcohol sponge

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:54365-014
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ISOPROPYL ALCOHOL (UNII: ND2M416302) (ISOPROPYL ALCOHOL - UNII:ND2M416302)	ISOPROPYL ALCOHOL	725 mg in 1 mL

POVIDONE-IODINE (UNII: 85H0HZU99M) (IODINE - UNII:9679TC07X4)

IODINE

8.3 mg
in 1 mL

Inactive Ingredients

Ingredient Name	Strength
CARBOMER COPOLYMER TYPE A (ALLYL PENTAERYTHRITOL CROSSLINKED) (UNII: 71DD5V995L)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
WATER (UNII: 059QF0KO0R)	
AMINOMETHYLPROPANOL (UNII: LU49E6626Q)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:54365-014-42	1 in 1 POUCH	04/09/2020	
1		26 mL in 1 APPLICATOR; Type 9: Other Type of Part 3 Combination Product (e.g., Drug/Device/Biological Product)		
2	NDC:54365-014-41	1 in 1 POUCH	05/21/2020	
2		10.5 mL in 1 APPLICATOR; Type 9: Other Type of Part 3 Combination Product (e.g., Drug/Device/Biological Product)		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	505G(a)(3)	04/09/2020	

Labeler - CareFusion 213 LLC (826496312)

Registrant - Becton, Dickinson and Company (832696038)

Establishment

Name	Address	ID/FEI	Business Operations
Becton, Dickinson and Company		124987988	manufacture(54365-014)

Establishment

Name	Address	ID/FEI	Business Operations
CareFusion 213 LLC		826496312	manufacture(54365-014) , pack(54365-014) , label(54365-014) , sterilize(54365-014) , analysis(54365-014)

Revised: 11/2023

CareFusion 213 LLC