

## **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

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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

EO





External Use Only

Professional Use Only

**⚠ WARNING • FLAMMABLE**



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Drug Facts

Active Ingredients
Purposes

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**Other information**

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**Inactive Ingredient**

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

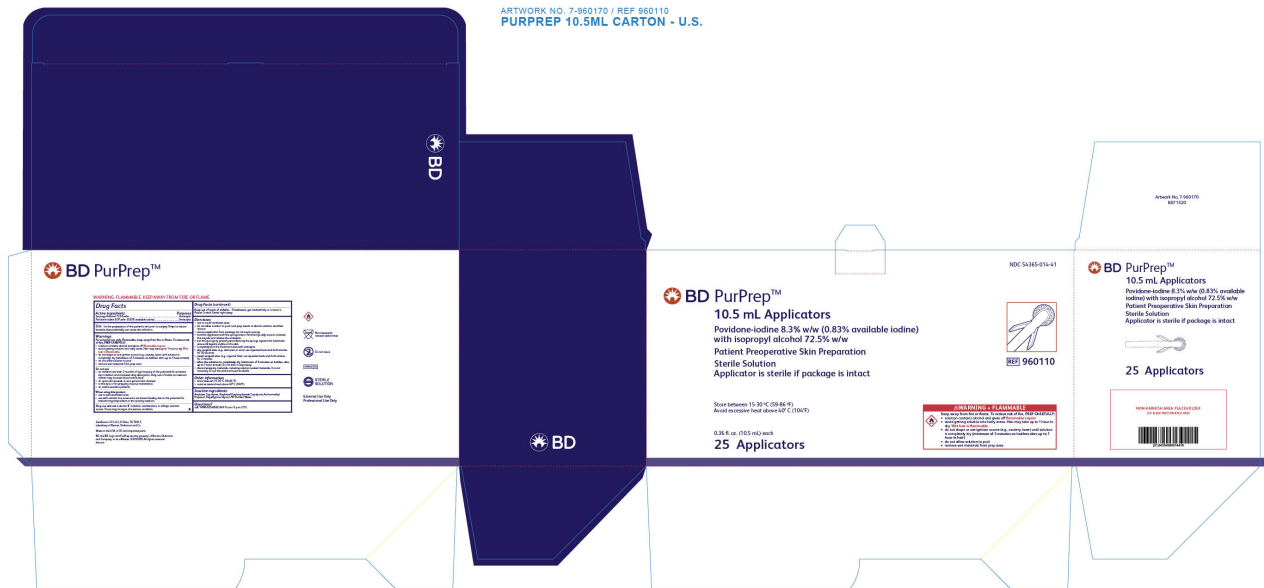
**Questions?** call 1-800-523-0502 (M-F 8 a.m.–5 p.m. CST)

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

<b>POVIDONE-IODINE</b> (UNII: 85H0HZU99M) (IODINE - UNII:9679TC07X4)	IODINE	8.3 mg in 1 mL
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### Inactive Ingredients

Ingredient Name	Strength
<b>CARBOMER COPOLYMER TYPE A (ALLYL PENTAERYTHRITOL CROSSLINKED)</b> (UNII: 71DD5V995L)	
<b>POLYETHYLENE GLYCOL, UNSPECIFIED</b> (UNII: 3WJQ0SDW1A)	
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>AMINOMETHYLPROPANOL</b> (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 2: Prefilled Drug Delivery Device/System (syringe, patch, etc.)		
2	NDC:54365-014-41	1 in 1 POUCH	05/21/2020	
2		10.5 mL in 1 APPLICATOR; Type 2: Prefilled Drug Delivery Device/System (syringe, patch, etc.)		

### 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)