

ZURAGARD BLUE- isopropyl alcohol solution
Zurex Pharma, Inc.

ZuraGard™
Isopropyl Alcohol (70% v/v) Solution
Patient Preoperative Skin Preparation

Active ingredient - 10.5 mL Applicator

Isopropyl alcohol 70% v/v

Purpose - 10.5 mL Applicator

Antiseptic

Uses - 10.5 mL Applicator

- for preparation of the skin prior to surgery
- helps reduce bacteria that potentially can cause skin infection

Warnings - 10.5 mL Applicator

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

To reduce risk of fire, PREP CAREFULLY:

- solution contains alcohol and gives off **flammable vapors**
- avoid getting solution into hairy areas. **Wet hair is flammable.** Hair may take up to 1 hour to dry.
- 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 patients allergic to isopropyl alcohol or any other ingredient in this product
- for lumbar puncture or in contact with the meninges
- on open skin wounds or as a general skin cleanser

When using this product

keep out of eyes, ears, and mouth. May cause serious or permanent injury if permitted to enter and remain. If contact occurs, rinse with cold water right away and contact a doctor.

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 - 10.5 mL Applicator

Follow all directions for use

- use with care in premature infants or infants under 2 months of age. These products may cause irritation or chemical burns.
- do not use when the sponge is already wet upon opening the package
- discard the applicator after a single use along with any portion of the solution which is not required to cover the prepped area. It is not necessary to use the entire amount available.

Getting Patient Ready for Solution:

- use in well-ventilated area
- do not microwave or heat the solution applicator
- apply to clean, completely dry, residue-free, intact skin
- when hair removal is necessary, use a surgical clipper on the morning of the surgery. If a wet shave is used, thoroughly remove all soap residues.

Activating the Applicator:

- remove applicator from package; do not touch sponge
- hold the applicator with the sponge down. Depress the end cap/button to release the antiseptic, solution will flow into the sponge.

When Applying Solution:

- completely wet the treatment area with antiseptic
- **dry surgical sites** (such as the abdomen or arm): use repeated back-and-forth strokes for 30 seconds
- **moist surgical sites** (such as inguinal fold): use repeated back-and-forth strokes for 2 minutes
- maximal treatment area for one applicator is approximately 8.4 in. x 8.4 in. (457 cm²)
- **do not allow solution to pool;** tuck prep towels to absorb solution, and then remove
- avoid getting solution into hairy areas. **Wet hair is flammable.** Hair may take up to 1 hour to dry.

After Applying Solution:

- to reduce the risk of fire, **wait until solution is completely dry** (minimum of 3 minutes on hairless skin; up to 1 hour in hair)

While Waiting for Solution to Completely Dry:

- do not drape or use ignition source (e.g., cautery, laser)
- check for pooled solution. Use sterile gauze to soak up pooled solution. Do not blot or wipe away because it may remove solution from skin.
- remove wet materials from prep area. Replace if necessary.

After Solution is Completely Dry:

- to reduce the risk of fire, begin draping and/or using cautery only after solution is completely dry and all wet materials are removed
- if incise drapes are used, apply directly to dry prep
- apply dressing following standard practices

Other information - 10.5 mL Applicator

- store between 15-30°C (59-86°F)
- avoid freezing and excessive heat above 40°C (104°F)
- the tint will slowly fade from the skin. Soap and water, or alcohol may be used to remove tint if desired.

Inactive ingredients - 10.5 mL Applicator

citric acid, methylene blue, methylparaben, propylparaben, purified water USP, trisodium citrate

Questions? - 10.5 mL Applicator

call 1-833-342-2798 (M-F 8AM-5PM CST).
www.zurexpharma.com

Active ingredient - 26 mL Applicator

Isopropyl alcohol 70% v/v

Purpose - 26 mL Applicator

Antiseptic

Uses - 26 mL Applicator

- for preparation of the skin prior to surgery
- helps reduce bacteria that potentially can cause skin infection

Warnings - 26 mL Applicator

**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
- do not use on an area smaller than 8.4 in x 8.4 in. Use a smaller applicator instead.
- solution contains alcohol and gives off **flammable vapors**
- avoid getting solution into hairy areas. **Wet hair is flammable.** Hair may take up to 1 hour to dry.
- 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

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irritation, sensitization, or allergic reaction occurs. These may be signs of a serious condition.

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If swallowed, get medical help or contact a Poison Control Center right away.

Directions - 26 mL Applicator

Follow all directions for use

- use with care in premature infants or infants under 2 months of age. These products may cause irritation or chemical burns.
- do not use when the sponge is already wet upon opening the package
- discard the applicator after a single use along with any portion of the solution which is not required to cover the prepped area. It is not necessary to use the entire amount available.

Getting Patient Ready for Solution:

- use in well-ventilated area
- do not microwave or heat the solution applicator
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When Applying Solution:

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- **dry surgical sites** (such as the abdomen or arm): use repeated back-and-forth strokes for 30 seconds
- **moist surgical sites** (such as inguinal fold): use repeated back-and-forth strokes for 2 minutes
- maximal treatment area for one applicator is approximately 13.2 in. x 13.2 in. (1126 cm²)
- **do not allow solution to pool;** tuck prep towels to absorb solution, and then remove
- avoid getting solution into hairy areas. **Wet hair is flammable.** Hair may take up to 1 hour to dry.

After Applying Solution:

- to reduce the risk of fire, **wait until solution is completely dry** (minimum of 3 minutes on hairless skin; up to 1 hour in hair)

While Waiting for Solution to Completely Dry:

- do not drape or use ignition source (e.g., cautery, laser)
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Questions? - 26 mL Applicator

call 1-833-342-2798 (M-F 8AM-5PM CST) www.zurexpharma.com

Principal Display Panel - 10.5 mL Applicator Label

Single Use

NDC 49823-100-01

ZuraGard™

Isopropyl Alcohol (70% v/v) Solution

Patient Preoperative Skin Preparation

Non-sterile Solution

Applicator is sterile if package is intact

Surgical Solution

For head, neck, and small prep areas

BLUE

10.5 mL (0.36 fl oz) APPLICATOR

Professional Use Only

Do not reuse

Not made with natural rubber latex

Warning

Flammable

Keep away from fire or flame.

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- do not allow solution to pool
- remove wet material from prep area

Manufactured for
Zurex Pharma, Inc.
Middleton, WI 53562

Single Use

NDC 49823-100-01

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Isopropyl Alcohol (70% v/v) Solution
Patient Preoperative Skin Preparation

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Surgical Solution

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BLUE

10.5 mL (0.36 fl oz) APPLICATOR

**Professional
Use Only**



Do not
reuse



Not made with
natural rubber latex

⚠ WARNING FLAMMABLE

Keep away from fire or flame.

To reduce risk of fire, PREP CAREFULLY:



- solution contains alcohol and gives off **flammable vapors**
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- do not allow solution to pool
- remove wet material from prep area

Manufactured for
Zurex Pharma, Inc.
Middleton, WI 53562

Label

Principal Display Panel - 26 mL Applicator Label

Single Use
NDC 49823-100-02

ZuraGard™
Isopropyl Alcohol (70% v/v) Solution
Patient Preoperative Skin Preparation

Non-sterile Solution

Applicator is sterile if package is intact

Surgical Solution

For large prep areas below the neck

BLUE

26 mL (0.9 fl oz) APPLICATOR

Professional Use Only

Do not reuse

Not made with natural rubber latex

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, or on an area smaller than 8.4 in. x 8.4 in. Use a smaller applicator instead.
- solution contains alcohol and gives off **flammable vapors**
- avoid getting solution into hairy areas. **Wet hair is flammable.** Hair may take up to 1 hour to dry.
- 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 material from prep area

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Middleton, WI 53562

Single Use

NDC 49823-100-02

ZuraGard™

Isopropyl Alcohol (70% v/v) Solution
Patient Preoperative Skin Preparation

Non-sterile Solution

Applicator is sterile if package is intact
Surgical Solution

For large prep areas below the neck

BLUE

26 mL (0.9 fl oz) APPLICATOR

**Professional
Use Only**



Do not
reuse



Not made with
natural rubber latex

WARNING FLAMMABLE

Keep away from fire or flame.

To reduce risk of fire, PREP CAREFULLY:



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Manufactured for
Zurex Pharma, Inc.
Middleton, WI 53562

Label

ZURAGARD BLUE

isopropyl alcohol solution

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:49823-100
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ISOPROPYL ALCOHOL (UNII: ND2M416302) (ISOPROPYL ALCOHOL - UNII:ND2M416302)	ISOPROPYL ALCOHOL	0.7 mL in 1 mL

Inactive Ingredients

Ingredient Name	Strength
TRISODIUM CITRATE DIHYDRATE (UNII: B22547B95K)	
WATER (UNII: 059QF0KO0R)	
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
METHYLENE BLUE (UNII: T42P99266K)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:49823-100-01	25 in 1 CARTON	02/27/2023	
1		10.5 mL in 1 POUCH; Type 0: Not a Combination Product		
2	NDC:49823-100-02	25 in 1 BOX	02/27/2023	
2		26 mL in 1 POUCH; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NDA	NDA210872	02/27/2023	

Labeler - Zurex Pharma, Inc. (043472453)

Establishment

Name	Address	ID/FEI	Business Operations
ExxonMobil		037961513	API MANUFACTURE(49823-100)

Establishment

Name	Address	ID/FEI	Business Operations
Ferndale Laboratories, Inc.		005320536	MANUFACTURE(49823-100) , ANALYSIS(49823-100)

Establishment

Name	Address	ID/FEI	Business Operations
Isomedix Operations Inc.		080419356	STERILIZE(49823-100)

Revised: 10/2023

Zurex Pharma, Inc.