

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:

210872Orig1s000

LABELING

BLUE
10.5 mL APPLICATORS

For head, neck, and small prep areas
Surgical Solution
Applicator is sterile if package is intact
Non-sterile Solution
Patient Preoperative Skin Preparation
Isopropyl Alcohol (70% v/v) Solution
ZuraGard™
Single Use

Single Use

NDC #####-###-##

Single Use

ZuraGard™

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Patient Preoperative Skin Preparation

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Drug Facts

Active ingredient
Isopropyl alcohol 70% v/v

Purpose
Antiseptic

Use

• for preparation of the skin prior to surgery • helps 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 on 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 • on larger punctures or in contact with the mucous membranes • on open skin wounds or as a general skin cleanser
When using this product, keep out of eyes, nose, and mouth. May cause serious or permanent injury if permitted to enter and remain. If contact occurs, rinse with cool water, tilt away and contact a doctor.
Stop use and ask a doctor if irritation, sensitization, or allergic reaction occurs. There may be signs of a sensitive condition.
Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.
Directions
Follow all directions for use.
• Use with care to prevent injury or infection under 2 months of age.
• Proper practice 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 using with any portion of the solution which is not required to cover the prepared area. It is not necessary to use the entire amount available.
Getting Patient Ready for Solution:
• Use in wet areas only.
• Do not microwave or heat the solution applicator.
• Apply to skin, completely dry, residue-free, intact skin.
• When hair removal is necessary, use a hospital clipper on the morning of the surgery. If wet areas remain, thoroughly remove all soap residue.

WARNING
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• remove wet material from prep area

2

Do not reuse

Do not use with natural rubber latex

Store between 15-30°C (59-86°F)
Avoid freezing and excessive heat above 40°C (104°F)
25 applicators, 0.36 fl oz (10.5 mL) each

Professional Use Only

25 applicators, 0.36 fl oz (10.5 mL) each

#6465 R01

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Manufactured for
Zurex Pharma, Inc.
Middleton, WI 53562
1-800-###-####
www.zurexpharma.com

LOT: XXXXXX

EXP.: YYYY-MMM-DD

Single Use
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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

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10.5 mL (0.36 fl oz) APPLICATOR
WARNING. FLAMMABLE. KEEP AWAY FROM FIRE OR FLAME.

Drug Facts	
Active ingredient	Purpose
sopropyl alcohol 70% v/v	Antiseptic
Uses • or preparation o the skin prior to surgery • helps reduce bacteria that potentially can cause skin in ection	
Warnings For external use only. Flammable, keep away from fire or flame. To reduce risk of fire, PREP CAREFULLY: ▪ solution contains alcohol and gives o 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 o 3 minutes on hairless skin up to 1 hour in hair) • do not allow solution to pool • remove wet materials rom prep area Do not use ▪ on patients allergic to isopropyl alcohol or any other ingredient in this product • or lumbar puncture or in contact with the meninges • on open skin wounds or as a general skin cleanser When using this product keep out o eyes, ears, and mouth May cause serious or permanent injury i permitted to enter and remain contact occurs, rinse with cold water right away and contact a doctor Stop use and ask a doctor i irritation, sensitization, or allergic reaction occurs hese may be signs o a serious condition Keep out o reach o children. swallowed, get medical help or contact a Poison Control Center right away	
Directions Follow all directions or use ▪ use with care in premature in ants or in ants under 2 months o age hese products may cause irritation or chemical burns ▪ do not use when the sponge is already wet upon opening the package ▪ discard the applicator a ter a single use along with any portion o the solution which is not required to cover the prepped area t is not necessary to use the entire amount available Getting Patient Ready or Solution: ▪ use in well-ventilated area ▪ do not microwave or heat the solution applicator ▪ apply to clean, completely dry, residue- ree, intact skin ▪ when hair removal is necessary, use a surgical clipper on the morning o the surgery a wet shave is used, thoroughly remove all soap residues Activating the Applicator: ▪ remove applicator rom package do not touch sponge ▪ hold the applicator with the sponge down Depress the end cap/button to release the antiseptic, solution will low 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- orth strokes or 30 seconds ▪ moist surgical sites (such as inguinal old) use repeated back-and- orth strokes or 2 minutes ▪ maximal treatment area or 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 A ter Applying Solution: ▪ to reduce the risk o ire, wait until solution is completely dry (minimum o 3 minutes on hairless skin up to 1 hour in hair) While Waiting or Solution to Completely Dry: ▪ do not drape or use ignition source (e g , cautery, laser) ▪ check or pooled solution Use sterile gauze to soak up pooled solution Do not blot or wipe away because it may remove solution rom skin ▪ remove wet materials rom prep area Replace i necessary A ter Solution is Completely Dry: ▪ to reduce the risk o ire, begin draping and/or using cautery only a ter solution is completely dry and all wet materials are removed ▪ i incise drapes are used, apply directly to dry prep ▪ apply dressing ollowing standard practices	
Other information • store between 15-30°C (59-86°) • avoid reezing and excessive heat above 40°C (104°) • the tint will slowly ade rom the skin Soap and water, or alcohol may be used to remove tint i desired	
Inactive ingredients citric acid, methylene blue, methylparaben, propylparaben, puri ied water USP, trisodium citrate	
Questions? call 1 800 ### ##### (M F 8AM 5PM CST) www.zurexpharma.com	

S0010v05



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- 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

ZuraGard™

Isopropyl Alcohol (70% v/v) Solution
Surgical Solution

For head, neck, and small prep areas

10.5 mL APPLICATOR

BLUE

Zurex Pharma, Inc.
Middleton, WI 53562
www.zurexpharma.com

0423x0L Rev01

Lot: XXXXXX

Exp.: YYYY-MMM

Single Use

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**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

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10.5 mL (0.36 fl oz) APPLICATOR

**Professional
Use Only**



Do not
reuse



Not made with
natural rubber latex

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Manufactured for
Zurex Pharma, Inc.
Middleton, WI 53562

690001 Rev01

Drug Facts

Active ingredient

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Purpose

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

Warnings

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

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- 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

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

Questions? call 1-800-###-#### (M-F 8AM-5PM CST).
www.zurexpharma.com

This is a representation of an electronic record that was signed electronically. Following this are manifestations of any and all electronic signatures for this electronic record.

/s/

THERESA M MICHELE
04/26/2019 02:38:27 PM