3M SOLUPREP S- chlorhexidine gluconate and isopropyl alcohol solution Solventum US OpCo LLC

3M SoluPrep™ S 26mL Brite Green Applicator

Drug Facts

Active ingredients

Chlorhexidine gluconate 2% w/v Isopropyl alcohol 70% v/v

Purpose

Antiseptic

Antiseptic

Uses

patient preoperative skin preparation:

- 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 26-mL applicator for head and neck surgery
- do not use on an area smaller than 8.4 in. x 15.6 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

Allergy Alert: This product may cause a severe allergic reaction. Symptoms may include:

- wheezing/difficulty breathing
- shock
- facial swelling
- hives
- rash

If an allergic reaction occurs, stop use and seek medical help right away.

Do not use

- on patients with known allergies to chlorhexidine gluconate 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.
- to avoid skin injury, care should be taken when removing drapes, tapes, etc.

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.
- discard the applicator after a single use along with any portion of the solution 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
- with sponge face parallel to the floor, press the cap end of the applicator. Solution will begin to flow into sponge.

When Applying Solution:

- 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
- maximal treatment area for one applicator is approximately 13.2 in. x 21.6 in. (285.2 in²).
- do not allow solution to pool; tuck prep towels to absorb solution, and then remove

- clean umbilicus with enclosed swabs when applicable.
- (Moisten swabs by pressing against solution-soaked sponge applicator.)
- avoid getting solution into hairy areas. **Wet hair is flammable**. Hair may take up to 1 hour to dry.
- when prepping skin folds, toes, or fingers, use a sterile-gloved hand to hold skin apart until completely 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 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. For early removal of surgical prep use soap and water or 70% Isopropyl Alcohol.

Inactive ingredients

acetyltri-n-butyl citrate, FD&C blue #1, FD&C yellow #5, purified water USP, Trisodium HEDTA

Questions?

call 1-800-228-3957 (Monday-Friday 7AM-6PM CST). www.3M.com/Medical 34-8727-1905-8

3M SoluPrep™ S 10.5mL Brite Green Applicator Drug Facts

Active ingredients

Chlorhexidine gluconate 2% w/v

Purpose

Antiseptic

Antiseptic

Uses

patient preoperative skin preparation:

- 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:

- 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

Allergy Alert: This product may cause a severe allergic reaction. Symptoms may include:

- wheezing/difficulty breathing
- shock
- facial swelling
- hives
- rash

If an allergic reaction occurs, stop use and seek medical help right away.

Do not use

- on patients with known allergies to chlorhexidine gluconate 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.
- to avoid skin injury, care should be taken when removing drapes, tapes, etc.

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.
- discard the applicator after a single use along with any portion of the solution 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
- grasp products by wrapping hand and fingers around the labeled portion of the applicator. Place thumb on the lever with sponge face parallel to the floor, snap lever to allow fluid to flow into sponge.

When Applying Solution:

- 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
- maximal treatment area for one applicator is approximately 8.4 in. x 15.6 in. (131.4 in²).
- 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.
- when prepping skin folds, toes, or fingers, use a sterile-gloved hand to hold skin apart until completely 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 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. For early removal of surgical prep use soap and water or 70% Isopropyl Alcohol.

Inactive ingredients

acetyltri-n-butyl citrate, FD&C blue #1, FD&C yellow #5, purified water USP, Trisodium HEDTA

Questions?

call 1-800-228-3957 (Monday-Friday 7AM-6PM CST). www.3M.com/Medical 34-8727-1906-6

3M SoluPrep™ S 10.5mL Clear Applicator Drug Facts

Active ingredients

Chlorhexidine gluconate 2% w/v Isopropyl alcohol 70% v/v

Purpose

Antiseptic

Antiseptic

Uses

patient preoperative skin preparation:

- 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:
- 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

Allergy Alert: This product may cause a severe allergic reaction. Symptoms may include:

- wheezing/difficulty breathing
- shock
- facial swelling
- hives
- rash

If an allergic reaction occurs, stop use and seek medical help right away.

Do not use

- on patients with known allergies to chlorhexidine gluconate 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.
- to avoid skin injury, care should be taken when removing drapes, tapes, etc.

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.
- discard the applicator after a single use along with any portion of the solution 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
- grasp product by wrapping hand and fingers around the labeled portion of the applicator. Place thumb on the lever with sponge face parallel to the floor, snap lever to allow fluid to flow into sponge.

When Applying Solution:

- 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
- maximal treatment area for one applicator is approximately 8.4 in. x 15.6 in. (131.4 in²)
- 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.
- when prepping skin folds, toes, or fingers, use a sterile-gloved hand to hold skin apart until completely 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 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)

Inactive ingredients

acetyltri-n-butyl citrate, purified water USP, Trisodium HEDTA

Questions?

call 1-800-228-3957 (Monday-Friday 7AM-6PM CST). www.3M.com/Medical 34-8727-1907-4

Principal Display Panel - 26mL Brite Green Applicator Label 3M

NDC 17518-082-01

STERILE EO

SoluPrep™ S

chlorhexidine gluconate (2% w/v) and isopropyl alcohol (70% v/v)

Patient Preoperative Skin Preparation

REF 67130

for large prep areas below the neck

Sterile Antiseptic Solution

Applicator is sterile if package is intact

Brite Green

0.9 fl oz • 26 mL

Single Use

Only

PRESS CAP DOWN

BACK AND FORTH

APPLICATION

External use only

Professional use only

Read Drug Facts information

before use

34-8727-1931-4

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(eep away from fire or flame

PREP CAREFULLY:

Do not use 26-mL applicator for

head and neck surgery, or on an area smaller than 8.4 in. x 15.6 in. Use a smaller applicator instead.

Solution contains alcohol and gives

Avoid getting solution into hairy

Hair may take up to 1 hour to dry areas. Wet hair is flammable.

ignition source (e.g., cautery, laser) until solution is completely d Do not drape or use

(minimum 3 minutes on hairless skin; up to one hour in hair)

Do not allow solution

to pool Remove wet materials from prep area

NDC 17518-082-01

STERILE EO

SoluPrep

chlorhexidine gluconate (2% w/v) and isopropyl alcohol (70% v/v) **Patient Preoperative Skin Preparation**

67130

for large prep areas below the neck

Sterile Antiseptic Solution

Applicator is sterile if package is intact

Brite Green



0.9 fl oz • 26 mL

LOT / EXP **IMPRINT AREA** (no print layer)



PRESS CAP DOWN

2 BACK AND FORTH **APPLICATION**

External use only Professional use only **Read Drug Facts information** before use

34-8727-1931-4

3M and SoluPrep are trademarks of 3M

STERILE EO

NDC 17518-082-01

SoluPrep™ S

chlorhexidine gluconate (2% w/v) and isopropyl alcohol (70% v/v)

Patient Preoperative Skin Preparation

for large prep areas below the neck

Sterile Antiseptic Solution

Applicator is sterile if package is intact

Brite Green

SoluPrep[™] S Sterile Antiseptic Solution is a sterile patient preoperative skin preparation.

Each unit dose applicator contains 0.9 fl oz (26 mL) of solution which covers a 13.2 in. x 21.6 in. area (approximate from shoulder to groin in an average full size adult).

For procedures requiring less coverage, a smaller applicator is available (67133 - Tinted or

67134 - Clear). The smaller applicator size contains 0.36 fl oz (10.5 mL) of solution which

covers an approximate 8.4 in. x 15.6 in. area. Do not use more than required for the area.

3M recommends all users participate in product in-service training prior to use. In-servicing is available on video, from your 3M sales representative or at the 3M website (www.3m.com).

SoluPrep™ S Sterile Antiseptic Solution is an antimicrobial skin preparation. It is recommended that the prep remain on the skin after the procedure for continued protection. The prep will gradually wear away. If however early removal is desired, use soap and water or 70% isopropyl alcohol.

REF **67130**

0.9 fl oz • 26 mL

Made in USA with Globally Sourced Materials

3M Company

2510 Conway Ave.

St. Paul, MN 55144 USA

1-800-228-3957

www.3M.com/Medical

Single Use Only

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Not Made With

Natural Rubber Latex

34-8727-1932-2

3M

STERILE

EO

NDC 17518-082-01

SoluPrep[™] S

chlorhexidine gluconate (2% w/v) and isopropyl alcohol (70% v/v) **Patient Preoperative Skin Preparation**

for large prep areas below the neck

Sterile Antiseptic Solution

Applicator is sterile if package is intact

Brite Green

AWARNING 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 15.6 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



Cautery

SoluPrep[™] S Sterile Antiseptic Solution is a sterile patient preoperative skin preparation. Each unit dose applicator contains 0.9 fl oz (26 mL) of solution which covers a 13.2 in. x 21.6 in. area (approximate from shoulder to groin in an average full size adult).

Faurusaandi, waa uanii isiba laaa aasaanana aanaallan annii aatau ia assailahla (67400 - Tintad

or 67134 - Clear). The smaller applicator size contains 0.36 fl oz (10.5 mL) of solution which covers an approximate 8.4 in. x 15.6 in. area. Do not use more than required for the area.

3M recommends all users participate in product in-service training prior to use. In-servicing is available on video, from your 3M sales representative or at the 3M website (www.3m.com).

SoluPrep™ S Sterile Antiseptic Solution is an antimicrobial skin preparation. It is recommended that the prep remain on the skin after the procedure for continued protection. The prep will gradually wear away. If however early removal is desired, use soap and water or 70% isopropyl alcohol.

№ 67130

0.9 fl oz • 26 mL



Made in USA with Globally Sourced Materials

■ 3M Company

2510 Conway Ave. St. Paul, MN 55144 USA 1-800-228-3957

www.3M.com/Medical

Single Use Only

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Not Made With Natural Rubber Latex

34-8727-1932-2

Principal Display Panel - 3M SoluPrep™ S 26mL Brite Green Applicator Pouch Label

3M

REF 67130

NDC 17518-082-01

Single

Use Only

SoluPrep™ S

chlorhexidine gluconate (2% w/v) and isopropyl alcohol (70% v/v)

Patient Preoperative Skin Preparation

for large prep areas below the neck
Sterile Antiseptic Solution
Applicator is sterile if package is intact

0.9 fl oz • 26 mL

Brite Green



REF 67130 NDC 17518-082-0

SoluPrep™S



chlorhexidine gluconate (2% w/v) and isopropyl alcohol (70% v/v)

Patient Preoperative Skin Preparation

for large prep areas below the neck

Sterile Antiseptic Solution

Applicator is sterile if package is intact

0.9 fl oz • 26 mL

Brite Green

Drug Facts

Active ingredients

Purpose

Chlorhexidine gluconate 2% w/v ... Isopropyl alcohol 70% v/v..... ..Antiseptic

Uses patient preoperative skin preparation: • 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 26-mL applicator for head and neck surgery
- do not use on an area smaller than 8.4 in. x 15.6 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

Allergy alert: This product may cause a severe allergic reaction. Symptoms may include:

wheezing/difficulty breathing
 shock
 facial swelling
 hives

If an allergic reaction occurs, stop use and seek medical help right away.

Do not use

- · on patients with known allergies to chlorhexidine gluconate 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.
- to avoid skin injury, care should be taken when removing drapes, tapes, etc.

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.

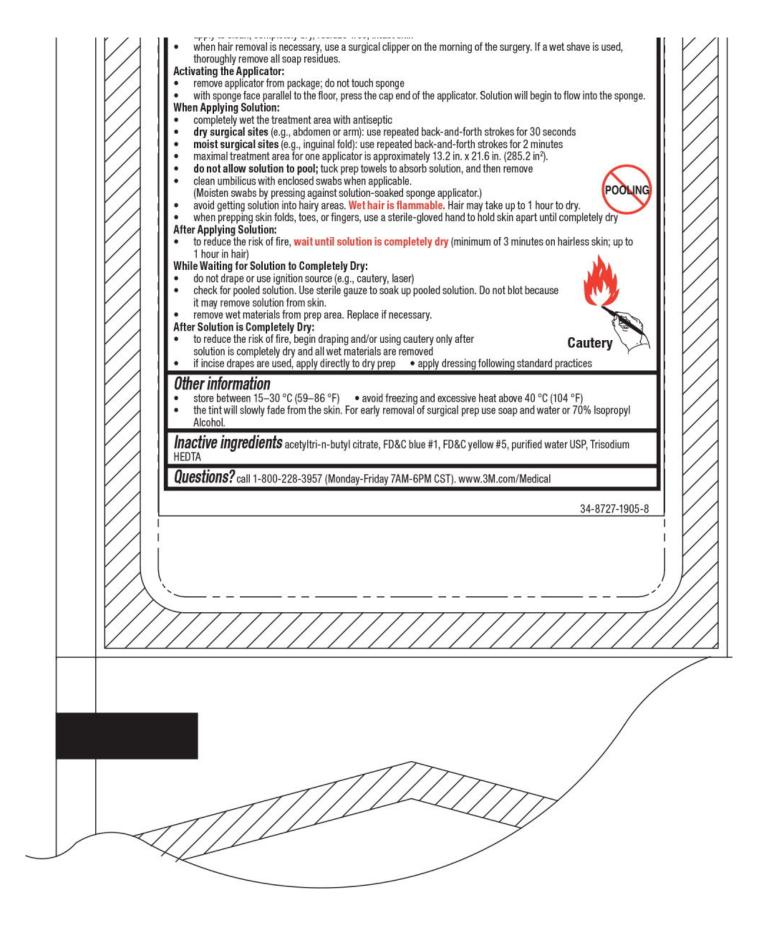
Directions (follow all directions for use)

- use with care in premature infants or infants under 2 months of age. These products may cause irritation or chemical burns
- discard the applicator after a single use along with any portion of the solution 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





Principal Display Panel - 10.5mL Brite Green Applicator Label 3M

STERILE EO

SoluPrep™ S

chlorhexidine gluconate (2% w/v) and isopropyl alcohol (70% v/v)

Patient Preoperative Skin Preparation

REF 67133

for head, neck, and small prep areas

Sterile Antiseptic Solution

Applicator is sterile if package is intact

Brite Green

0.36 fl oz • 10.5 mL

Single Use

Only

3M and

SoluPrep

are trademarks

of 3M.

SNAP

BACK AND FORTH

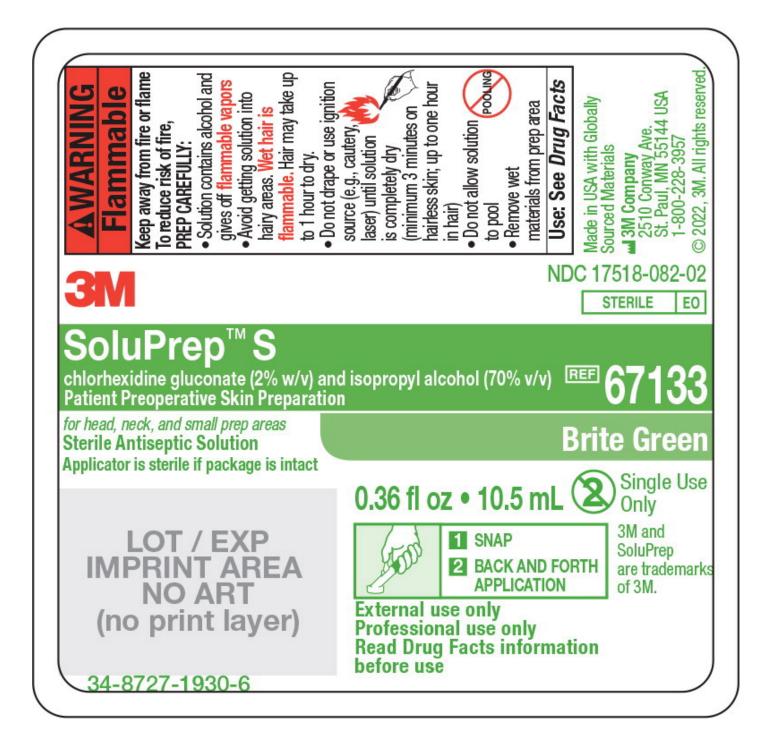
APPLICATION

External use only

Professional use only

Read Drug Facts information

before use



34-8727-1930-6

Principal Display Panel - 10.5mL Brite Green Applicator Insert Label 3M

STERILE EO NDC 17518-082-02

SoluPrep™ S

chlorhexidine gluconate

(2% w/v) and isopropyl

alcohol (70% v/v)

Patient Preoperative Skin Preparation

for head, neck, and small prep areas

Sterile Antiseptic Solution

Applicator is sterile if package is intact

Brite Green

SoluPrep™ S Sterile Antiseptic Solution is a sterile patient preoperative skin preparation. Each unit dose applicator contains 0.36 fl oz (10.5 mL) of solution which covers a 8.4 in. x 15.6 in. area.

3M recommends all users participate in product in-service training prior to use. In-servicing is available on video, from your 3M sales representative or at the 3M website (www.3m.com).

SoluPrep™ S Sterile Antiseptic Solution is an antimicrobial skin preparation. It is recommended that the prep remain on the skin after the procedure for continued protection. The prep will gradually wear away. If however early removal is desired, use soap and water or 70% isopropyl alcohol.

REF **67133**

0.36 fl oz • 10.5 mL

Made in USA with Globally

Sourced Materials

3M Company

2510 Conway Ave.

St. Paul, MN 55144 USA

1-800-228-3957

www.3M.com/Medical

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34-8727-1933-0

3M

STERILE

NDC 17518-082-02

SoluPrep[™] S

Not Made With Natural Rubber Latex

Single Use Only

chlorhexidine gluconate (2% w/v) and isopropyl alcohol (70% v/v)

Patient Preoperative Skin Preparation

for head, neck, and small prep areas

Sterile Antiseptic Solution

Applicator is sterile if package is intact

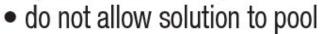
Brite Green

AWARNING 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)



· remove wet materials from prep area



SoluPrep[™] S Sterile Antiseptic Solution is a sterile patient preoperative skin preparation. Each unit dose applicator contains 0.36 fl oz (10.5 mL) of solution which covers a 8.4 in. x 15.6 in. area.

3M recommends all users participate in product in-service training prior to use. In-servicing is available on video, from your 3M sales representative or at the 3M website (www.3m.com).

SoluPrep[™] S Sterile Antiseptic Solution is an antimicrobial skin preparation. It is recommended that the prep remain on the skin after the procedure for continued protection. The prep will gradually wear away. If however early removal is desired, use soap and water or 70% isopropyl alcohol.

REF 67133 0.36 fl oz • 10.5 mL

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Principal Display Panel - 3M SoluPrep™ S 10.5mL Brite Green Applicator Pouch Label

3M

REF 67133

NDC 17518-082-02

Single

Use Only

SoluPrep™ S

chlorhexidine gluconate (2% w/v) and isopropyl alcohol (70% v/v)

Patient Preoperative Skin Preparation

for head, neck, and small prep areas

Sterile Antiseptic Solution

Applicator is sterile if package is intact

0.36 fl oz • 10.5 mL

Brite Green



67133

NDC 17518-082-02

SoluPrep™S



chlorhexidine gluconate (2% w/v) and isopropyl alcohol (70% v/v)
Patient Preoperative Skin Preparation

for head, neck, and small prep areas

Sterile Antiseptic Solution

Applicator is sterile if package is intact

0.36 fl oz • 10.5 mL

Brite Green

Drug Facts

Active ingredients

Purpose

 Antiseptic Antiseptic

Uses patient preoperative skin preparation: • 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:

- · 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

Allergy alert: This product may cause a severe allergic reaction. Symptoms may include:

wheezing/difficulty breathing
 shock
 facial swelling
 hives
 rash

If an allergic reaction occurs, stop use and seek medical help right away.

Do not use

- on patients with known allergies to chlorhexidine gluconate 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.
- to avoid skin injury, care should be taken when removing drapes, tapes, etc.

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. discard the applicator after a single use along with any portion of the solution 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 grasp product by wrapping hand and fingers around the labeled portion of the applicator. Place thumb on the lever with sponge face parallel to the floor, snap lever to allow fluid to flow into sponge. When Applying Solution: 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 maximal treatment area for one applicator is approximately 8.4 in. x 15.6 in. (131.4 in²). POOLING 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. when prepping skin folds, toes, or fingers, use a sterile-gloved hand to hold skin apart until completely 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 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 Cautery 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. For early removal of surgical prep use soap and water or 70% Isopropyl Inactive ingredients acetyltri-n-butyl citrate, FD&C blue #1, FD&C yellow #5, purified water USP, Trisodium **HEDTA** Questions? call 1-800-228-3957 (Monday-Friday 7AM-6PM CST). www.3M.com/Medical 34-8727-1906-6

Principal Display Panel - 10.5 mL Clear Applicator Label

3M

NDC 17518-083-02

STERILE EO

SoluPrep™ S

chlorhexidine gluconate (2% w/v) and isopropyl alcohol (70% v/v)

Patient Preoperative Skin Preparation

REF 67134

for head, neck, and small prep areas

Sterile Antiseptic Solution

Applicator is sterile if package is intact

Clear

0.36 fl oz • 10.5 mL

SNAP

BACK AND FORTH

APPLICATION

External use only

Professional use only

Read Drug Facts information

before use

Single Use

Only

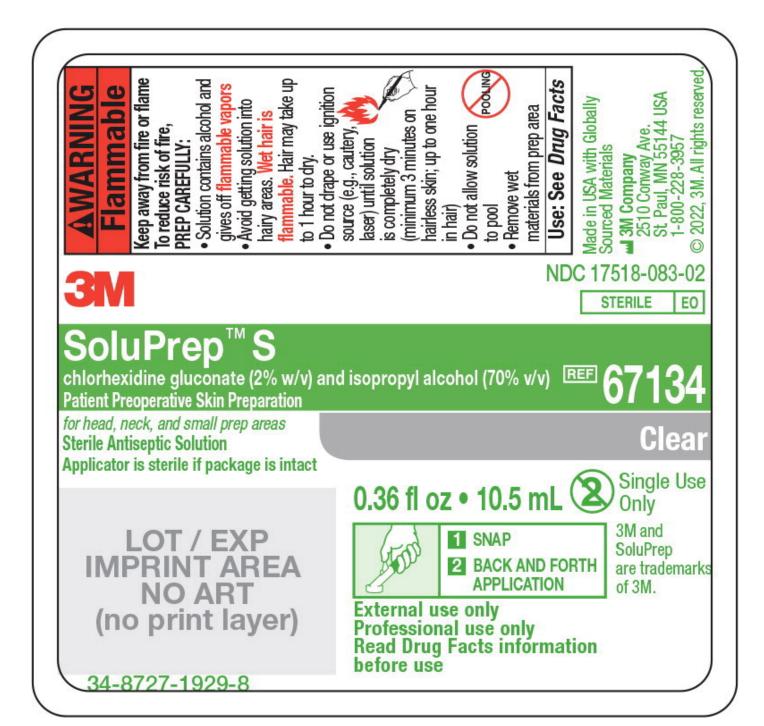
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34-8727-1929-8



Principal Display Panel - 10.5mL Clear Insert Label

3M

STERILE EO

NDC 17518-083-02

SoluPrep™ S

chlorhexidine gluconate (2% w/v) and isopropyl alcohol (70% v/v)

Patient Preoperative Skin Preparation

for head, neck, and small prep areas

Sterile Antiseptic Solution

Applicator is sterile if package is intact

Clear

Not Made With

Natural Rubber Latex

Single Use Only

SoluPrep™ S Sterile Antiseptic Solution is a sterile patient preoperative skin preparation. Each unit dose applicator contains 0.36 fl oz (10.5 mL) of solution which covers a 8.4 in. x 15.6 in. area.

3M recommends all users participate in product in-service training prior to use. In-servicing is available on video, from your 3M sales representative or at the 3M website (www.3m.com).

SoluPrep™ S Sterile Antiseptic Solution is an antimicrobial skin preparation. It is recommended that the prep remain on the skin after the procedure for continued protection. The prep will gradually wear away.

If however early removal is desired, use soap and water or 70% isopropyl

REF **67134**

alcohol.

0.36 fl oz • 10.5 mL

Made in USA with Globally Sourced Materials

3M Company

2510 Conway Ave.

St. Paul, MN 55144 USA

1-800-228-3957

www.3M.com/Medical

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3M

STERILE

EO

NDC 17518-083-02

SoluPrep[™] S

Not Made With Natural Rubber Latex

chlorhexidine gluconate (2% w/v) and isopropyl alcohol (70% v/v)



Patient Preoperative Skin Preparation

for head, neck, and small prep areas

Sterile Antiseptic Solution

Applicator is sterile if package is intact

Clear

AWARNING 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)



remove wet materials from prep area



SoluPrep[™] S Sterile Antiseptic Solution is a sterile patient preoperative skin preparation. Each unit dose applicator contains 0.36 fl oz (10.5 mL) of solution which covers a 8.4 in. x 15.6 in. area.

3M recommends all users participate in product in-service training prior to use. In-servicing is available on video, from your 3M sales representative or at the 3M website (www.3m.com).

SoluPrepTM S Sterile Antiseptic Solution is an antimicrobial skin preparation. It is recommended that the prep remain on the skin after the procedure for continued protection. The prep will gradually wear away. If however early removal is desired, use soap and water or 70% isopropyl alcohol.



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Principal Display Panel - 3M SoluPrep™ S 10.5mL Clear Applicator Pouch Label 3M

REF 67134

NDC 17518-083-02

Single

Use Only

SoluPrep™ S

chlorhexidine gluconate (2% w/v) and isopropyl alcohol (70% v/v)

Patient Preoperative Skin Preparation

for head, neck, and small prep areas

Sterile Antiseptic Solution

Applicator is sterile if package is intact

0.36 fl oz • 10.5 mL

Clear



[™] 67134

NDC 17518-083-02



chlorhexidine gluconate (2% w/v) and isopropyl alcohol (70% v/v)
Patient Preoperative Skin Preparation

for head, neck, and small prep areas

Sterile Antiseptic Solution

Applicator is sterile if package is intact

0.36 fl oz • 10.5 mL

Clear

Drug Facts

Active ingredients

Purpose

 ..Antiseptic

Uses patient preoperative skin preparation: • 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:
- 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

Allergy alert: This product may cause a severe allergic reaction. Symptoms may include:

If an allergic reaction occurs, stop use and seek medical help right away.

Do not use

- on patients with known allergies to chlorhexidine gluconate 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.
- · to avoid skin injury, care should be taken when removing drapes, tapes, etc.

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.



discard the applicator after a single use along with any portion of the solution 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 grasp product by wrapping hand and fingers around the labeled portion of the applicator. Place thumb on the lever with sponge face parallel to the floor, snap lever to allow fluid to flow into sponge. When Applying Solution: 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 maximal treatment area for one applicator is approximately 8.4 in. x 15.6 in. (131.4 in²). 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. when prepping skin folds, toes, or fingers, use a sterile-gloved hand to hold skin apart until completely 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 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 Cauter 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) Inactive ingredients acetyltri-n-butyl citrate, purified water USP, Trisodium HEDTA Questions? call 1-800-228-3957 (Monday-Friday 7AM-6PM CST), www.3M.com/Medical 34-8727-1907-4

chlorhexidine gluconate and isopropyl alcohol solution

Product Information

Product Type HUMAN OTC DRUG Item Code (Source) NDC:17518-082

Route of Administration TOPICAL

Active Ingredient/Active Moiety Ingredient Name Basis of Strength Chlorhexidine Gluconate (UNII: MOR84MUD8E) (Chlorhexidine UNII:R4KO0DY52L) Chlorhexidine Gluconate Gluconate Chlorhexidine Gluconate in 1 mL Isopropyl Alcohol (UNII: ND2M416302) (Isopropyl Alcohol - UNII:ND2M416302) Isopropyl Alcohol Chlorhexidine Gluconate in 1 mL

Inactive Ingredients				
Ingredient Name	Strength			
Acetyltributyl Citrate (UNII: 0ZBX0N59RZ)				
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)				
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)				
Water (UNII: 059QF0KO0R)				
Trisodium Hedta (UNII: K3E0U7O8KI)				

P	Packaging					
#	Item Code	Package Description	Marketing Start Date	Marketing End Date		
1	NDC:17518- 082-01	1 in 1 POUCH	01/23/2023			
1		26 mL in 1 APPLICATOR; Type 0: Not a Combination Product				
2	NDC:17518- 082-02	1 in 1 POUCH	01/23/2023			
2		10.5 mL in 1 APPLICATOR; Type 0: Not a Combination Product				

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
NDA	NDA208288	01/23/2023		

3M SOLUPREP S

chlorhexidine gluconate and isopropyl alcohol solution

Prod	luct	Inform	ation
			acioii

Product Type HUMAN OTC DRUG Item Code (Source) NDC:17518-083

Active Ingredient/Active Moiety				
Ingredient Name	Basis of Strength	Strength		
Chlorhexidine Gluconate (UNII: MOR84MUD8E) (Chlorhexidine - UNII:R4KO0DY52L)	Chlorhexidine Gluconate	20 mg in 1 mL		
Isopropyl Alcohol (UNII: ND2M416302) (Isopropyl Alcohol - UNII:ND2M416302)	Isopropyl Alcohol	0.7 mL in 1 mL		

Inactive Ingredients				
Ingredient Name Strength				
Acetyltributyl Citrate (UNII: 0ZBX0N59RZ)				
Water (UNII: 059QF0KO0R)				
Trisodium Hedta (UNII: K3E0U7O8KI)				

Packaging					
# Item Code	Package Description	Marketing Start Date	Marketing End Date		
NDC:17518- 083-02	1 in 1 POUCH	01/23/2023			
1	10.5 mL in 1 APPLICATOR; Type 0: Not a Combination Product				

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
NDA	NDA208288	01/23/2023		

Labeler - Solventum US OpCo LLC (006173082)

Establishment				
Name	Address	ID/FEI	Business Operations	
3M Company		830016148	ANALYSIS(17518-082, 17518-083)	

Revised: 4/2024 Solventum US OpCo LLC