

ACL11CH NERVE BLOCK - regional anesthesia kit
Smiths Medical ASD, Inc.

CHLORAPREP ONE-STEP (chlorhexidine gluconate and isopropyl alcohol) solution
[CareFusion 213 LLC]

Active ingredients

Chlorhexidine gluconate 2% w/v

Isopropyl alcohol 70% v/v

Purposes

Antiseptic

Antiseptic

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 the risk of fire, PREP CAREFULLY:

- 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 patients with known allergies to chlorhexidine gluconate or isopropyl alcohol
- 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

- use with care in premature infants or infants under 2 months of age. These products may cause irritation or chemical burns.

- use in a well ventilated area
- maximal treatment area for one applicator is approximately 4 in. x 5 in. (130 cm²)
- remove applicator from package; do not touch sponge
- hold the applicator with the sponge down. Pinch wings only once to activate the ampule 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 gentle repeated back-and-forth strokes for 30 seconds
- moist surgical sites (e.g., inguinal fold): use gentle 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 the applicator after a single use along with any portion of the solution not required to cover the prep area. It is not necessary to use the entire amount available.

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 the tint if desired.

Inactive ingredients

- FD&C yellow #6 dye
- USP purified water

Package Label Display Panel

NDC 054365-400-11

3 ml

APPLICATORS

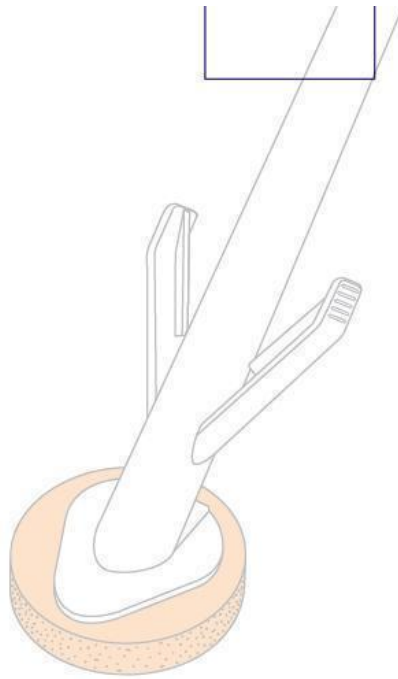
Hi-Lite Orange®

Single Use
Latex Free

Applicator is STERILE
if package is intact

Store between 15-30 °C (59-86 °F)
Avoid freezing and excessive heat
above 40 °C (104 °F)

25 applicators



ChloraPrep® With Tint

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

Patient Preoperative Skin Preparation

WARNING
FLAMMABLE

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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)
- avoid getting solution into hairy areas.
- **Wet hair is flammable.** Hair may take up to 1 hour to dry.
- do not allow solution to pool
- remove wet material from prep area

Package Label Display Panel

CLINT. PHARMACEUTICALS INCORPORATED

REF ACL11CH

To Reorder Call:
1-800-677-5022

PREP COMPONENTS:

- 1 Towel
- 3 Gauze Sponges
- 1 * ChloraPrep® One Step (Directions For Use enclosed)

PROCEDURAL COMPONENTS:

- 1 Fenestrated Drape
- 1 Needle Stick Pad
- 1 Flexible Extension Unit
- 1 18G X 1 1/2 In. Needle
- 1 25G X 1 1/2 In. Needle
- 1 Plastic Syringe (10ml, Luer Lock)
- 1 Plastic Syringe (5ml, Luer Lock)
- 2 Plastic Syringes (3ml, Luer Lock)

*Warnings: Flammable • Do not use with electrocautery procedures - see enclosed Directions For Use
Do not use for Lumbar Puncture or in contact with the meninges.
Sterility Note: Outer applicator is sterile

NERVE BLOCK

WARNINGS:

- A needle stick with a contaminated needle may cause infectious disease.
- The use of excessive force while placing needles into the stick pad may cause the needle to protrude through the bottom of the tray which may result in a contaminated needle stick.

PRECAUTIONS:

- **Use Aseptic technique.** To help prevent needle-stick injuries, needles should not be recapped or purposely bent. If excessive resistance is met during needle insertion, do not force the needle as damage may occur. To help avoid needle breakage, do not attempt to straighten a bent needle; discard it and complete the procedure with a replacement needle.
- After use, place sharps in a suitable sharps container. Dispose of contaminated product in a safe manner according to Centers for Disease Control and Prevention, USA and Federal/State/Local regulations (EPA, OSHA) and health care facility guidelines or local equivalent.
- Do NOT Recycle.
- To be used only by individuals familiar with nerve block procedures. For specific techniques and procedures, refer to standard textbooks.

STORE AT CONTROLLED ROOM TEMPERATURE

All other names and marks mentioned are the trademarks, trademarks or service marks of their respective owners.

Manufactured for:
Clint Pharmaceuticals
629 Shute Lane
Old Hickory, TN 37138



STERILE EO Rx ONLY
Caution - Do Not Reuse - Not made with natural rubber latex - Do not use if package is damaged - Sterilized using ethylene oxide - Caution: Federal (U.S.A.) law restricts this device to sale by or on the order of a physician

MADE IN USA

PLTACL11CH REV. 000 01/14



(01) 2 0351688 08128 2

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ACL11CH NERVE BLOCK

regional anesthesia kit kit

Product Information

Product Type	MEDICAL DEVICE	Item Code (Source)	NHRIC:55553-482
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Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NHRIC:55553-482-02	30 in 1 CASE		
1		1 in 1 PACKAGE, COMBINATION		

Quantity of Parts

Part #	Package Quantity	Total Product Quantity
Part 1	1 APPLICATOR	3 mL

Part 1 of 1

CHLORAPREP ONE-STEP

chlorhexidine gluconate and isopropyl alcohol solution

Product Information

Item Code (Source)	NDC:54365-400
Route of Administration	TOPICAL

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	0.70 mL in 1 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:54365-400-11	3 mL in 1 APPLICATOR		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NDA	NDA020832	08/18/2006	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
premarket notification	K965017	01/14/2014	

Labeler - Smiths Medical ASD, Inc. (137835299)

Establishment

Name	Address	ID/FEI	Business Operations
Smiths Medical ASD, Inc.		137835299	manufacture

Establishment

Name	Address	ID/FEI	Business Operations
CareFusion 213 LLC		830430778	manufacture

Revised: 4/2014

Smiths Medical ASD, Inc.