TRISEPTIN HAND AND BODY ANTISEPTIC- alcohol lotion HEALTHPOINT, LTD

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

TRISEPTIN Hand and Body Antiseptic – alcohol lotion CareFusion

Drug Facts

Active ingredient

Ethyl alcohol 70% v/v

PURPOSE

Antiseptic

Uses

Surgical Hand Scrub:

• Significantly reduces the number of microorganisms on the hands, forearms and body prior to surgery or patient care.

Patient Preoperative Skin Preparation:

- For preparation of the skin prior to surgery or an injection.
- Helps reduce bacteria that can potentially cause skin infection.

Warnings

- Flammable, keep away from fire or flame.
- For external use only.
- Do not use
- if you are allergic to or have a known or suspected hypersensitivity to any ingredient in this product.
- on or near the eyes, mucous membranes, genital skin, or mouth. If product gets into the eyes, flush immediately with water.
- Avoid contact with broken skin.
- **Stop use and ask doctor if** irritation and redness develop. If condition persists for more than 72 hours consult a physician.
- Keep out of reach of children.
- If swallowed, get medical help or contact a Poison Control Center right away.

Directions

Surgical Hand Scrub:

- Clean under nails with a nail pick. Nails should be maintained with a 1 mm free edge.
- Wet hands and forearms.
- Dispense palmful (approx. 7 ml) of TRISEPTIN Scrub into the palm of one hand.

- Twist fingertips of the opposite hand, working TRISEPTIN under the nails.
- Transfer TRISEPTIN to the opposite hand and repeat with fingertips of the other hand.
- Rub TRISEPTIN over the hands and up the forearms to just past the elbow, paying particular attention to the nails, cuticles and interdigital spaces for 90 seconds.
- Rinse and repeat the procedure to just below the elbows. Rinse completely.

Patient Preoperative Skin Preparation:

- Apply to cleanse the surgical site and surrounding area 12 hours and 6 hours prior to surgery.
- Clean the surgical area.
- Place a palmful (approx. 7 ml) of TRISEPTIN to the surgical site and surrounding area and rub for 90 seconds paying particular attention to the surgical area.
- Rinse and repeat.
- Rinse completely.

Other information

- Store at 20-25° C (68-77° F).
- Avoid freezing and excessive heat.
- Protect from light until use.
- Shake well.

Inactive ingredients

Benzethonium chloride, citric acid, cocamine oxide, fragrance, glyceryl laurate, hydroxypropylcellulose, phenylethyl alcohol, phosphoric acid, polyoxyl 40 stearate, propyl gallate, propylene glycol, purified water, zinc pyrithione.

Questions?

Please call **1-800-523-0502** (M-F 8 a.m.-5 p.m. CST) or visit our web site www.triseptin.com.

Marketed by:

CareFusion

Leawood, KS 66211

Manufactured for:

Healthpoint, Ltd.

Fort Worth, TX 76107

by DPT Laboratories, Ltd.

San Antonio, Texas 78215

REORDER NO. 0064-1050-04

PATENT NO. 6,110,908

4 fl oz (118 ml)

129478-0411

PRINCIPAL DISPLAY PANEL

NDC 0064-1050-04

Triseptin[®]

Ethyl alcohol 70% v/v

Hand & Body Antiseptic

Surgical Hand Scrub

Used by surgeons in hospital operating rooms

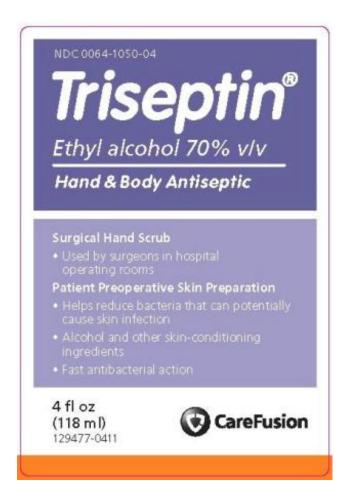
Patient Preoperative Skin Preparation

- Helps reduce bacteria that can potentially cause skin infection
- Alcohol and other skin-conditioning ingredients
- Fast antibacterial action

4 fl oz (118 ml) 129477-0411

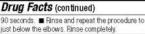
CareFusion

PACKAGE LABEL.PRINCIPAL DISPLAY PANEL









Patient Preoperative Skin Preparation: ■ Apply to cleanse the surgical site and surrounding area 12 hours and 6 hours prior to surgery. ■ Clean the surgical area. ■ Place a palmful (approx 7 ml) of TRISEPTIN® to the surgical site and surrounding

TRISEPTIN® to the surgical site and surrounding area and rub for 90 seconds paying particular attention to the surgical area. ■ Rinse and repeat. ■ Rinse completely.

Other information

■ Store at 20-25° C (68-77° F). ■ Avoid freezing and excessive heat. ■ Protect from light until use, ■ Shake well.

Inactive ingredients

Benzethorium chloride, citric acid, cocamine oxide fragrance, glyceryl laurate, hydroxypropylcellulose, phenylethyl alcohol, phosphoric acid, polycoyl 40 stearate, propyl gallate, propylene glycol, purified water. zinc pyrithione.

Questions?

Please call 1-800-523-0502 (M-F 8 a.m.-5 p.m.



TRISEPTIN HAND AND BODY ANTISEPTIC

alcohol lotion

Product Information

Product Type HUMAN OTC DRUG Item Code (Source) NDC:0064-1050

Route of Administration TOPICAL

Active Ingredient/Active Moiety

Ingredient Name Basis of Strength Strength
ALCOHOL (UNII: 3K9958 V90M) (ALCOHOL - UNII:3K9958 V90M)
ALCOHOL (UNII: 3K9958 V90M) ALCOHOL .7 mL in 1 mL

Inactive Ingredients Ingredient Name Strength BENZETHONIUM CHLORIDE (UNII: PH41D05744) CITRIC ACID MONOHYDRATE (UNII: 2968 PHW8 QP) COCAMINE OXIDE (UNII: QWA2IZI6FI) GLYCERYL LAURATE (UNII: Y98611C087) HYDROXYPROPYL CELLULOSE (UNII: RFW2ET671P) PHENYLETHYL ALCOHOL (UNII: ML9LGA7468) PHOSPHORIC ACID (UNII: E4GA8884NN) POLYOXYL 40 STEARATE (UNII: 13A4J4NH91) PROPYL GALLATE (UNII: 8D4SNN7V92) PROPYLENE GLYCOL (UNII: 6DC9Q167V3) WATER (UNII: 059QF0KO0R) PYRITHIONE ZINC (UNII: R95302RHZ5)

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Product	Characte	ristics

Color WHITE (white to off-white) Score

Shape			Size			
Flavor			Imprint Cod	e		
Contains						
Packaging						
# Item Code	Package Description	Marketin	g Start Date	Marketing End Date		
1 NDC:0064-1050-04	118 mL in 1 BOTTLE, PLASTIC					
Marketing Information						
Marketing Category	Application Number or Monograp	h Citation	Marketing Start I	Date Marketing End Dat		

04/01/2002

Labeler - HEALTHPOINT, LTD (965634504)

OTC monograph not final part333E

Establishment							
Name	Address	ID/FEI	Business Operations				
DPT LABORATORIES, LTD		832224526	MANUFACTURE				

Revised: 1/2012 HEALTHPOINT, LTD