

TRISEPTIN- alcohol lotion
DFB Technology 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

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 a doctor if:

- irritation and redness develop
- condition persists for more than 72 hours

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.
- 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 upright 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 **1-800-323-9088** (M-F 8 a.m. - 5 p.m. CST).

Distributed by:
Becton Dickinson
El Paso, TX 79912

Manufactured for:
DFB Technology, Ltd.
Fort Worth, TX 76107
by DPT Laboratories, Ltd.
San Antonio, TX 78215
4 fl oz (118 mL)
140840-1116

PRINCIPAL DISPLAY PANEL

NDC 70472-101-04
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)

140839-1116

BD

REORDER NO. 0064-1050-04

PACKAGE LABEL.PRINCIPAL DISPLAY PANEL

NDC 70472-101-04

Triseptin[®]

Ethyl alcohol 70% v/v

Hand & Body Antiseptic

Surgical Hand Scrub

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**4 fl oz
(118 ml)**

140839-1116



REORDER NO. 0064-1050-04

Drug Facts

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Ethyl alcohol 70% v/vAntiseptic

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Bar code
goes here

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PEEL
HERE

Drug Facts (continued)

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Drug Facts (continued)

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alcohol lotion

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:70472-101
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	0.7 mL in 1 mL

Inactive Ingredients

Ingredient Name	Strength
BENZETHONIUM CHLORIDE (UNII: PH41D05744)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
COCAMINE OXIDE (UNII: QWA2IZI6FI)	
GLYCERYL LAURATE (UNII: Y98611C087)	
HYDROXYPROPYL CELLULOSE (UNII: RFW2ET671P)	
PHENYLETHYL ALCOHOL (UNII: ML9LGA7468)	
PHOSPHORIC ACID (UNII: E4GA8884NN)	
POLYOXYL 40 STEARATE (UNII: 13A4J4NH9I)	
PROPYL GALLATE (UNII: 8D4SNN7V92)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0K00R)	
PYRITHIONE ZINC (UNII: R953O2RHZ5)	

Product Characteristics

Color	white (white to off-white)	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70472-101-04	118 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	09/15/2017	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333E	09/15/2017	

Labeler - DFB Technology Ltd (965516164)

Establishment

Name	Address	ID/FEI	Business Operations
DPT Laboratories		832224526	manufacture(70472-101)

Revised: 12/2017

DFB Technology Ltd