PREVAIL ONE STEP- povidone-iodine and alcohol gel
Productos Urologos de Mexico, S.A. de C.V.

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.

Prevail® One-Step Gel

ACTIVE INGREDIENTS

Ethanol 62% (v/v)

Povidone-Iodine USP 5.0% (0.5% available iodine)

PURPOSES

Antiseptic

Antiseptic

USE

For preparation of the patient's skin prior to surgery. Helps reduce bacterial 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**.
- 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 to pool
- Remove wet materials from prep area
- If prep accidentally drips into hair, allow to dry completely

Do not use

- on children less than 2 months of age because of the potential for excessive skin irritation and increased drug absorption. Daily use of iodine on newborn infants may increase blood iodine level.
- on iodine sensitive patients
- on open skin wounds or as a general skin cleanser
- in the eyes or for prepping mucous membranes

When using this product

use in well ventilated area.

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

- to reduce risk of fire the following strategies are recommended:
    - at the end of prep, discard any portion of the solution which is not required to cover the prep area. It is not necessary to use the entire amount available.
    - use in a well ventilated area
    - 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
    - tuck prep towels to absorb solution, and then remove
    - remove wet materials from prep area
    - drape after solution is completely dry
- Hold the bottle in an upright position
- Twist the applicator head in the direction of the arrow until it stops
- Firmly push the applicator head down into the bottle until a snap is heard
- Invert bottle and gently squeeze to dispense solution
- Once applicator sponge has been primed with solution it is not necessary to continue to squeeze the bottle
- When applicable, press cotton-tipped swab securely against impregnated applicator head to wet, then clean umbilicus
- Apply thin, even coat to operative site
- If applying prep to a tight area (e.g., neck, skin folds), insert prep towels underneath to absorb excess solution
- Remove any excess prep with absorbent towels or gauze
- Discard prepping materials, including solution soaked materials
- Wait until prep is dry (3 minutes or more) on skin before draping or using ignition sources
- Remove with soap and water

OTHER INFORMATION

- Store at USP room temperature, 20-25°C (66-77°F)
- Avoid excessive heat (not to exceed 104°F/40°C)

INACTIVE INGREDIENTS

- Citric Acid
- Glycerin
- Hydroxypropylcellulose
- Nonoxynol-10
- Simethicone

- Sodium Hydroxide
- USP purified water

Questions?

call: **1-800-523-0502** (M-F 8 AM-5 PM CST)

PRINCIPAL DISPLAY PANEL

Cat. **4VAIL** NDC 57613-008-59

Prevail® One Step Gel and Applicator
Topical Patient Preoperative Skin Prep

Povidone Iodine USP 5% (0.5% Available Iodine)
with 62% Ethanol (v/v) 59ml

Single application provides rapid initial kill and persistent broad spectrum antimicrobial activity.

For Single Use Only
Contents sterile if package is intact.
Solution not exposed to sterilant.

LATEX FREE

Lot No.

Exp.

Contents
1 Applicator with Urethane Sponge
2 Cotton-Tipped Swabs
1 Blotting Towel

WARNING: FLAMMABLE, KEEP AWAY FROM FIRE OR FLAME.

U.S. components assembled in Mexico except as indicated:
Cotton-Tipped Swabs Made in China

U.S. Patent Nos. 5,916,882, 6,488,665 and 7,201,525.

CareFusion, Leawood, KS 66211 USA

Label

PREVAIL ONE STEP povidone-iodine and alcohol gel

Product Information

Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:57613-008
Route of Administration	TOPICAL	**DEA Schedule**	

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
POVIDONE-IODINE (UNII: 85H0HZU99M) (IODINE - UNII:9679TC07X4)	IODINE	5 mg in 1 mL
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	0.62 mL in 1 mL

Inactive Ingredients

Ingredient Name	Strength
DIMETHICONE (UNII: 92RU3N3Y1O)	
HYDROXYPROPYL CELLULOSE (TYPE H) (UNII: RFW2ET671P)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
GLYCERIN (UNII: PDC6A3C0OX)	
NONOXYNOL-10 (UNII: K7O76887AP)	
WATER (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:57613-008-59	1 in 1 POUCH		
1		59 mL in 1 APPLICATOR		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	06/01/1997	

Labeler - Productos Urologos de Mexico, S.A. de C.V. (812552219)

Registrant - CareFusion 213 LLC (826496312)

Establishment

Name	Address	ID/FEI	Business Operations
Productos Urologos de Mexico, S.A. de C.V.		812552219	LABEL(57613-008) , PACK(57613-008)

Revised: 12/2012 Productos Urologos de Mexico, S.A. de C.V.