SCRUB CARE POVIDONE IODINE TOPICAL PAINT- povidone-iodine solution CareFusion 213 LLC

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.

Scrub Care® Povidone Iodine Topical Solution Paint

Active ingredient

Povidone-Iodine, USP 10% (1.0% available iodine)

Purpose

Antiseptic

Uses

- Prepping intact skin and mucous membranes prior to surgery
- Helps reduce bacteria that potentially can cause skin infection

Warnings

- For external use only
- Avoid use on persons allergic to iodine
- Do not use in the eyes
- Discontinue use if irritation and redness develop. If condition persist for more than 72 hours consult a doctor.

Stop use and ask a doctor if

- Skin shows symptoms of irritation, sensitivity, redness, pain or swelling
- In case of deep puncture wounds or serious burns

Keep out of reach of children.

If swallowed, get medical help or contact a Poison Control Center right away.

Directions

- Use full strength
- Apply solution to operative site following povidone iodine scrub application
- Using a circular motion, start at incision site and move outward
- Remove all soiled underdrapes
- Do not allow solution to pool

Other information

Store at room temperature

- Avoid excessive heat (above 104°F/40°C)
- Protect from freezing
- Latex Free

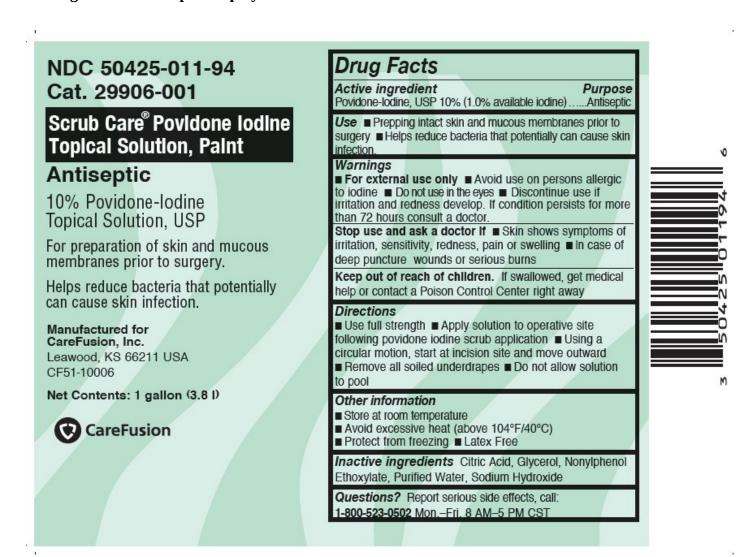
Inactive ingredients

Citric Acid, Glycerol, Nonylphenol Ethoxylate, Purified Water, Sodium Hydroxide

Questions?

Report serious side effects, call: 1-800-523-0502 Mon.-Fri. 8 AM-5 PM CST

Package/Label Principal Display Panel



Scrub Care 1 gal PVPI Paint Label

Product Type HUMAN OTC DRUG LABEL Item Code (Source) NDC:50425-011

Active Ingredient/Active Moiety

J J		
Ingredient Name	Basis of Strength	Strength
PO VIDO NE-IO DINE (IO DINE)	IODINE	10 mg in 1 mL

Inactive Ingredients	
Ingredient Name	Strength
CITRIC ACID MO NO HYDRATE	
GLYCERIN	
WATER	
SO DIUM HYDRO XIDE	

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:50425-011-59	59 mL in 1 BOTTLE		
2	NDC:50425-011-98	118 mL in 1 BOTTLE		
3	NDC:50425-011-97	236 mL in 1 BOTTLE		
4	NDC:50425-011-96	472 mL in 1 BOTTLE		
5	NDC:50425-011-95	944 mL in 1 BOTTLE		
6	NDC:50425-011-94	3785 mL in 1 BOTTLE		

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	0 1/0 1/20 0 1	

Labeler - CareFusion 213 LLC (831684456)

Registrant - CareFusion 213 LLC (831684456)

Establishment				
Name	Address	ID/FEI	Business Operations	
Thatcher Company		041307356	MANUFACTURE(50425-011)	

Establishment			
Name	Address	ID/FEI	Business Operations
Productos Urologos de Mexico, S.A. de C.V		8 12552219	LABEL(50425-011), PACK(50425-011)

Revised: 8/2012 CareFusion 213 LLC