

BIOTRONIX HEALTHCARE- povidone iodine sponge
Biotronix Healthcare Industries, Inc.

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.

Active ingredient

Povidone Iodine 10%

Purpose

Antiseptic

Warnings

For external use only. Do not use in the eyes.

Stop use and ask a doctor if Skin shows symptoms of **irritation, sensitivity, redness, pain or swelling**

Direction

- Wet hands and forearms with water
- Clean under nails with nail cleaner
- Scrub for 3 minutes with the impregnated brush
- Pay close attention to the nails, cuticles, and interdigital spaces
- Rinse thoroughly with running water
- Repeat

Inactive ingredients

Hydroxyethylcellulose, Nonoxynol ethoxylate, Purified Water

Uses For cleansing hands and arms prior to surgery

Other information

- Store at room temperature
- Avoid excessive heat above 40 °C (104 °F)
- Protect from freezing
- Latex free

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.



Biotronix
Healthcare®



Surgical Scrub Brush/Sponge w/ Nail Cleaner

Povidone-Iodine 10%

REF: OR411002

NDC:

Drug Facts

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MANUFACTURED FOR:
BIOTRONIX HEALTHCARE INDUSTRIES INC.
Ft. Lauderdale, Florida USA
www.biotronixhealthcare.com



BIOTRONIX HEALTHCARE

povidone iodine sponge

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:71389-101
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
POVIDONE-IODINE (UNII: 85H0HZU99M) (IODINE - UNII:9679TC07X4)	IODINE	100 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0K00R)	
HYDROXYETHYL CELLULOSE (100 MPAS AT 2%) (UNII: R33S7TK2EP)	
NONOXYNOL-10 (UNII: K7O76887AP)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:71389-101-01	20 mL in 1 POUCH; Type 2: Prefilled Drug Delivery Device/System (syringe, patch, etc.)	05/03/2018	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part333C	05/03/2018	

Labeler - Biotronix Healthcare Industries, Inc. (065762392)

Revised: 5/2018

Biotronix Healthcare Industries, Inc.