POVIDONE-IODINE SCRUB SWABSTICK - povidone-iodine solution H and P Industries, Inc. dba Triad Group

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.

DRUG FACTS

ACTIVE INGREDIENT

Povidone Iodine USP 7.5% w/v (equivalent to 0.75% titratable iodine)

PURPOSE

Antiseptic

USES

- Health Care Antiseptic for preparation of the skin prior to surgery
- First Aid Antiseptic to help prevent the risk of infection in minor cuts, scrapes and burns

WARNINGS

For external use only.

Do not

- use in the eyes
- apply over large areas of the body
- use on individuals who are allergic or sensitive to iodine
- use as a first aid antiseptic for longer than 1 week unless directed by a doctor

Ask a doctor in case of

- deep or puncture wounds
- animal bites
- serious burns

Stop use and ask a doctor

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

Keep out of reach of children

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

DIRECTIONS

For preparation of the skin prior to surgery

- clean the affected area
- apply to the operative site prior to surgery

As a first aid antiseptic

- clean the affected area
- apply a small amount of this product to the area 1-3 times daily
- may be covered with a sterile bandage
- if bandaged, let dry first

OTHER INFORMATION

Store at room temperature 15° - 30° C (59° - 86° F)

INACTIVE INGREDIENTS

citric acid, glycerin, purified water, sodium hydroxide, Surfonic N-95

LABEL INFORMATION TRIAD

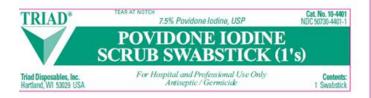
Cat. No. 10-4401 NDC 50730-4401-1

7.5% Povidone Iodine, USP POVIDONE IODINE SCRUB SWABSTICK (1's)

Triad Disposables, Inc. Hartland, WI 53029 USA

For Hospital and Professional Use Only Antiseptic / Germicide

Contents: 1 Swabstick





CARTON INFORMATION

TRIADINE

Cat. No. 10-4401 NDC 50730-4401-1

Povidone Iodine, USP POVIDONE IODINE SCRUB SWABSTICK (1's)

Antiseptic / Germicide

Triad Disposables, Inc. Brookfield, WI 53045

MADE IN USA

For Hospital and Professional Use Store at Room Temperature

Contents: 50 Pouches 1 Swabstick per Pouch



POVIDONE-IODINE SCRUB SWABSTICK

povidone-iodine solution

Product Information			
Product T ype	HUMAN OTC DRUG	Item Code (Source)	NDC:50730-4401
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	Basis of Strength	Strength
povidone-iodine (UNII: 85H0HZU99M) (povidone-iodine - UNII:85H0HZU99M)	po vido ne-io dine	.075 mg in 1 mI
Inactive Ingredients		
Ingredient Name		Strength
citric acid monohydrate (UNII: 2968PHW8QP)		
glycerin (UNII: PDC6A3C0OX)		
nonoxynol-9 (UNII: 48Q180SH9T)		
polyethylene glycol 300 (UNII: 5655G9Y8AQ)		
sodium hydroxide (UNII: 55X04QC32I)		
sodium phosphate, monobasic, monohydrate (UNII: 593YOG76RN)		
water (UNII: 059QF0KO0R)		

Packaging			
# Item Code	Package Description	Marketing Start Date	Marketing End Date
1 NDC:50730-4401-1	50 in 1 BOX		
1	1 in 1 POUCH		
1	1.7 mL in 1 APPLICATOR		
Marketing Information			

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333	0 1/14/19 8 7	

Labeler - H and P Industries, Inc. dba Triad Group (050259597)

Registrant - H and P Industries, Inc. dba Triad Group (050259597)

Establishment

Name	Address	ID/FEI	Business Operations
Hand P Industries, Inc. dba Triad Group		050259597	manufacture

Revised: 11/2009

Hand P Industries, Inc. dba Triad Group