

POVIDONE-IODINE PREP 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 10% w/v (equivalent to 1% 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
- remove swab by stick
- 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, Makon 8, purified water, sodium hydroxide

POUCH INFORMATION

TRIAD

Cat. No. 10-4101

NDC 50730-4101-1

10% Povidone Iodine, USP

POVIDONE IODINE

SWABSTICKS (1's)

Antiseptic / Germicide

For Hospital and Professional Use Only

Triad Disposables, Inc.

Brookfield, WI 53045 USA

Contents:

1 Swabstick



CARTON INFORMATION
TRIAD

Cat. No. 10-4101
 NDC 50730-4101-1

10% Povidone Iodine, USP
 POVIDONE IODINE
 SWABSTICKS (1's)

Antiseptic / Germicide
 For Hospital and Professional Use Only

Triad Disposables, Inc.
 Brookfield, WI 53045 USA

Contents:
 50 Pouches
 1 Swabstick per Pouch



POVIDONE-IODINE PREP SWABSTICK

povidone-iodine solution

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:50730-4101
Route of Administration	TOPICAL, EPIDURAL, PERCUTANEOUS		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
povidone-iodine (UNII: 85H0HZU99M) (povidone-iodine - UNII:85H0HZU99M)	povidone-iodine	.10 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
citric acid monohydrate (UNII: 2968PHW8QP)	
glycerin (UNII: PDC6A3C0OX)	
sodium hydroxide (UNII: 55X04QC32I)	
water (UNII: 059QF0K00R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:50730-4101-1	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	06/21/1985	

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
H and P Industries, Inc. dba Triad Group		050259597	manufacture

Revised: 11/2009

Hand P Industries, Inc. dba Triad Group