POVIDONE-IODINE PREP SWABSTICKS - povidone-iodine solution 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, nonoxynol-8, purified water, sodium hydroxide

POUCH INFORMATION TRIAD

Cat. No. 10-4102 NDC 50730-4102-3

10% Povidone Iodine, USP POVIDONE IODINE SWABSTICKS (3's)

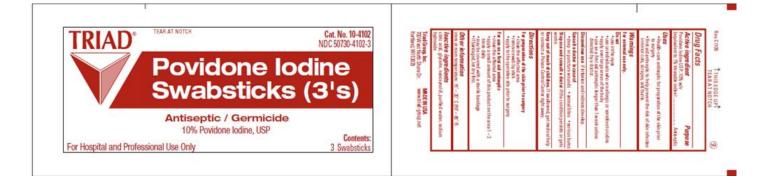
Antiseptic / Germicide 10% Povidone Iodine, USP

For Hospital and Professional Use Only

Contents: 3 Swabsticks

Triad Group, Inc. 700 West North Shore Drive Hartland, WI 53029

MADE IN USA www.triad-group.net



CARTON INFORMATION TRIAD

Cat. No. 10-4102 NDC 50730-4102-3

POVIDONE IODINE SWABSTICKS (3's)

Antiseptic / Germicide

For Hospital and Professional Use 10% Povidone Iodine, USP

25 Pouches 3 Swabsticks per Pouch



povidone-iodine solution			
Product Information			
Product T ype	HUMAN OTC DRUG	Item Code (Source)	NDC:50730-4102
Route of Administration	TOPICAL, EPIDURAL, PERCUTANEOUS		
Active Ingredient/Active Mo	iety		
Ing	Basis of Strength	Strength	
povidone-iodine (UNII: 85H0HZU99M	po vido ne -io dine	0.10 mg in 1 mL	
Inactive Ingredients			
	Ingredient Name		Strength
citric acid monohydrate (UNII: 2968			
glycerin (UNII: PDC6A3C0OX)			
glycerin (UNII: PDC6A3C0OX) sodium hydroxide (UNII: 55X04QC32	I)		

Packaging							
#	Item Code	Package Description	Marketing	g Start Date	Ma	rketing End Date	
I NI	DC:50730-4102-3	25 in 1 BOX					
1		3 in 1 POUCH					
1		1.7 mL in 1 APPLICATOR					
Ma	rketing Infor	mation					
	rketing Infor	mation Application Number or Monog	raph Citation	Marketing Start	Date	Marketing End Date	

Labeler - Triad Group (050259597)

Establishment								
Name	Address	ID/FEI	Business Operations					
Triad Group		050259597	manufacture					

Revised: 3/2010

Triad Group