POVIDONE IODINE PLUS - povidone-iodine gel 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% (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 infection in minor cuts, scrapes and burns

WARNINGS

For external use only.

Do not use

- in the eyes
- on individuals who are allergic or sensitive to iodine
- as a first aid antiseptic 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

• 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

• 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 15° - 30° C (59° - 86° F)

INACTIVE INGREDIENTS

citric acid, glycerin, hydroxyethylcellulose, sodium hydroxide, water

PACKAGE INFORMATION

Cat. No. 11-LP14 NDC 50730-8214-8

TRIAD Plus

POVIDONE IODINE PREP GEL

Povidone Iodine, USP 10% Topical Gel

- **ANTISEPTIC** for preparation of the skin prior to surgery. Helps reduce bacteria that potentially can cause skin infection.
- For Hospital and Professional use.

4 Fluid Ounces (118 ml)

Triad Group, Inc. 700 West North Shore Drive Hartland, WI 53029 Made In USA www.triad-group.net Cat. No. 11-LP14 NDC 50730-8214-8



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Povidone-Iodine, USP 10% Topical Gel

Antiseptic / Germicide

- ANTISEPTIC for preparation of the skin prior to surgery. Helps reduce bacteria that potentially can cause skin infection.
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4 Fluid Ounces (118 ml)

Drug Facts

Active Ingredient

Povidone lodine, 10% w/v

(equivalent to 1% titratable iodine)......Antiseptic

Purpose

Uses ■ Health care antiseptic for preparation of the skin prior to surgery ■ First aid antiseptic to help prevent the risk of skin infection in minor cuts, scrapes, and burns

Warnings

For external use only. Do not use ■ in the eyes ■ on individuals who are allergic or sensitive to iodine ■ as a first aid antiseptic longer than 1 week unless directed by a doctor

Stop use and ask a doctor if irritation and redness develop

Ask a doctor in case of ■ deep or puncture wounds
■ animal bites ■ serious burns

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 area ■ apply to the operative site prior to surgery

For use as a first aid antiseptic: ■ clean the affected area ■ apply a small amount of this product on the area 1-3 times daily ■ may be covered with a sterile bandage ■ if bandaged, let dry first

Other Information store at 15° - 30° C (59° - 86° F)

Inactive Ingredients citric acid, glycerin, hydroxyethylcelluose, sodium hydroxide, water

Triad Group, Inc. 700 West North Shore Drive Hartland, WI 53029 Made In USA www.triad-group.net Rev Rn2

POVIDONE IODINE PLUS

povidone-iodine gel

Dro	duct	Infor	mation
PIO			IIIAIIOII

Product TypeHUMAN OTC DRUGItem Code (Source)NDC:50730-8214

Route of Administration TOPICAL

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
povidone-iodine (UNII: 85H0 HZU99 M) (povidone-iodine - UNII:85H0 HZU99 M)	po vido ne-io dine	0.10 g in 1 mL	

Inactive Ingredients			
Ingredient Name	Strength		
CITRIC ACID MO NO HYDRATE (UNII: 2968 PHW8 QP)			
GLYCERIN (UNII: PDC6A3C0OX)			
HYDROXYETHYL CELLULOSE (2000 CPS AT 1%) (UNII: S38J6RZN16)			
SO DIUM HYDRO XIDE (UNII: 55X04QC32I)			
WATER (UNII: 059QF0KO0R)			

P	ackaging			
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:50730-8214-8	118 mL in 1 BOTTLE		

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	04/01/2001	

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

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

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

Revised: 4/2010 Hand P Industries, Inc. dba Triad Group