

TRIADINE - 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

- Surgical hand scrub for health care professionals
- 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

As a surgical hand scrub for use by health care professionals

- clean under nails with a nail pick
- nails should be maintained with 1 millimeter free edge
- wet hands and forearms
- apply milliliter (teaspoon) or palmful to hands and forearms
- scrub thoroughly paying particular attention to nails, cuticles and interdigital spaces
- rinse and repeat scrub

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, nonoxynol-9, PEG-300, sodium hydroxide, sodium phosphate, water

LABEL INFORMATION

Triad

Cat. No. 10-8308

NDC 50730-8308-3

scrub

POVIDONE IODINE
SOLUTION, USP

7.5% Povidone Iodine (0.75% titratable iodine)

Antiseptic / Germicide

Antiseptic for preparation of the skin prior to surgery. Helps reduce bacteria that potentially can cause skin infection


First aid antiseptic to help prevent the risk of infection in minor cuts, scrapes and burns

For hospital and professional use only

Triad Disposables, Inc.

Brookfield, WI 53045 USA

8 fl. oz.(236 ml)



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Brookfield, WI 53045 USA

8

fl. oz. (236 mL)

Drug Facts

Active ingredient	Purpose
Povidone iodine USP, 7.5% w/v (equivalent to 0.75% titratable iodine) ... Antiseptic	

Uses ■ Surgical hand scrub for health care professionals ■ 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 ■ use as a first aid antiseptic longer than one week unless directed by a doctor ■ use on individuals who are allergic or sensitive to iodine ■ apply over large areas of the body

Discontinue use and ask a doctor ■ if condition persists for more than 72 hours ■ 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
As a surgical hand scrub for use by health care professionals ■ clean under nails with a nail pick ■ nails should be maintained with 1 millimeter free edge ■ wet hands and forearms ■ apply 5 milliliters (teaspoon) or palmful to hands and forearms ■ scrub thoroughly paying particular attention to nails, cuticles and interdigital spaces ■ rinse and repeat scrub

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

Drug Facts (cont'd)

Other information
Store at room temperature: 15° – 30° C (59° – 86° F)

Inactive ingredients
citric acid, glycerin, nonoxynol-9, PEG-6, purified water, sodium hydroxide, sodium phosphate

Triad Disposables, Inc.
Brookfield, WI 53045
MADE IN USA
www.triad-group.net

Rev. A0906

VENDOR: PLEASE PLACE
UPN (UCC/EAN-128)
(01) 00350730830836
(01) 00350730830836

TRIADINE			
povidone-iodine solution			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:50730-8308
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	.075 mL in 1 mL

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:50730-8308-3	236 mL in 1 BOTTLE		

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