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

Triadine

Cat. No. 10-8328 NDC 50730-8328-6

POVIDONE IODINE, USP SCRUB SOLUTION 7.5% Topical Solution

Antiseptic / Germicide

PRE-SURGICAL HAND SCRUB. Significantly reduces the number of micro-organisms on hands and forearms prior to surgery or patient 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

For External Use Only!

128 Fluid Ounces (3.785L)

Triad Disposables, Inc. Brookfield, WI 53045 MADE IN USA



TRIADINE									
povidone-iodine solution									
Product Information									
Product T ype	HUMAN OTC DRUG	Item Code (Source)	NDC:50730-8328						
Route of Administration	TOPICAL, EPIDURAL, PERCUTANEOUS								
Active Ingredient/Active Met									
Active Ingredient/Active Moiety									
Ing	redient Name	Basis of Streng	th Strength						

povidone-iodine

	tive Ingredients						
Ingredient Name						Strength	
citric	acid monohydrate	(UNII: 2968PHW8QP)					
glyce	rin (UNII: PDC6A3C0	OX)					
nono	xynol-9 (UNII: 48Q18	0 S H9 T)					
polye	thylene glycol 300 ((UNII: 5655G9Y8AQ)					
sodiu	m hydroxide (UNII: 5	55X04QC32I)					
sodium phosphate, monobasic, monohydrate (UNII: 593YOG76RN)							
watei	r (UNII: 059QF0KO0F	k)					
Pac	kaging						
#	Item Code	Package Description	Marketing	g Start Date	Ma	rketing End Date	
1 ND	C:50730-8328-6	3.785 L in 1 BOTTLE					
	rketing Infor	mation					
Ma	0	Application Number or Monograph Citation		Marketing Start Date			
	rketing Category	Application Number or Monog	raph Citation	Marketing Star	t Date	Marketing End Dat	

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