SPLINTER FIRST AID KIT- povidone iodine, Honeywell Safety Products USA, Inc

Disclaimer: This drug has not been found by FDA to be safe and effective, and this labeling has not been approved by FDA. For further information about unapproved drugs, click here.

Splint First Aid Kit: 02-10-70X

Active ingredient

Povidone iodine 10% (equivalent to 1% titrateable iodine)

Purpose

First aid antiseptic

Uses

• first aid antiseptic to help prevent infection in minor cuts, scrapes and burns

Warnings

For external use only

Ask a doctor before use if you have

- deep or puncture wounds
- animal bites
- serious burns

Stop use and ask a doctor if

- condition worsens or persists for more than 72 hours
- irritation and redness develops

Keep out of reach of children.

If swallowed, get medical help or contact a Poison Control Center right away

Directions

- clean the affected area
- apply1 to 3 times daily
- may be covered with a sterile bandage
- if bandaged, let dry first

Other information

- do not use on individuals who are allergic or sensitive to iodine
- store at controlled temperature 59-86°F (15-30°C)
- do not use if pouch is open or torn
- discard after each use

Inactive ingredients

nonoxynol 9, water

Questions

1-800-430-5490

Principal Display Panel

Splinter First Aid Kit

Drug Facts (continued)

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 Ask a doctor believe use

 * in case of deep or puncture wounds, animal bites, or serious burns

 Stop use and ask a doctor if
 • condition peniets or gets worso

 Keep out of mesh of children. If evaluowed, get medical help or contast a Poison Control Center right away

 Direction * deen the affected area.

 • apply a small amount of this product on the area 1 to 3 times daily

 * may be covered with a storile bandage * if bandaged, lot day first

 Other information

 • do not use on individuals who are allergic or sensitive to lodine * store at room temperature: 15:50° C (50-66° F)

 • do not use if social social

 • decard after each use.

 Inacctive ingredients

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Splinter First Aid Kit

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Splinter First Aid Kit One-Forceps Two-Adhesive Bandages, 1 x 3 in (2.5 x 7.6 cm) One-Antiseptic Wipe PVP:

02-10-70)

SPLINTER FIRST AID KIT

povidone iodine, kit						
Product Information						
Product Type HUMA	N OTC DRUG	Item Code (S	Source)	NĽ	0C:0498-9002	
Packaging						
# Item Code	Package Descriptio		n Marketing Start D		Marketing End Date	
1 NDC:0498-9002-00 1 in 1 KIT			12/29/2017			
1 1 in 1 POU	CH; Type 0: Not a Combin	ation Product				
Quantity of Parts						
Part # Package Quantity			Total Product Quantity			
Part 1 3 POUCH		1 mL				
Part 1 of 1						
NORTH PVP IODINE	WIDE					
povidone-iodine 10% swab						
Product Information						
Item Code (Source)	NDC:0498-0120					
Route of Administration	TOPICAL					
Active Ingredient/Active M	oiety					
Ingredient Name			B	asis of Stre	ngth Strength	
PO VIDO NE-IO DINE (UNII: 85H0 HZU99M) (IO DINE - UNII:96		79TC07X4)	IOE	DINE	10 mg in 1 mL	
Inactive Ingredients						
	Ingredient Name				Strength	
NONOXYNOL-9 (UNII: 48Q180SH	T)					
WATER (UNII: 059QF0KO0R)						
Packaging						
# Item Code	Package Descripti	on	Marketin	g Start Date	Marketing End Date	
1 NDC:0498-0120-00 0.3 mL in 1						
Marketing Informatio	1					

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date		
unapproved drug other		12/29/2017			
Marketing Information					
Marketing Info	rmation				
Marketing Infor Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date		
		Marketing Start Date	Marketing End Date		

Labeler - Honeywell Safety Products USA, Inc (079287321)

Registrant - Honeywell Safety Products USA, Inc (079287321)

Establishment

Name	Address	ID/FEI	Business Operations
Honeywell Safety Products USA, Inc		079287321	pack(0498-9002)

Establishment

Name	Address	ID/FEI	Business Operations
Sion Biotext Medical		532775194	manufacture(0498-0120)

Revised: 8/2018

Honeywell Safety Products USA, Inc