#### ALPHA ONE- povidone-iodine gel AOSS Medical Supply, Inc.

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.

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## Active Ingredients:

Povidone-iodine USP 10% w/v

#### Purpose

Antiseptic

#### Uses

- Health care antiseptic for preparation of the skin prior to surgery
- First aid antiseptic to help reducce bacteria that potentially can cause skin infection
- For hospital and professional use

## 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 before use if you have

• deep or puncture wounds, animal bites or serious burns.

# Stop use and ask a doctor if

• irritation or 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

# <u>As a first aid antiseptic</u>

- 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

# Inactive Ingredients

Disodium hydrogen phosphate, Glycerin, Hydroxyethyl cellulose, Purified water

# Other Information

Store at room temperature.

	<b>822C0</b>				
	<b>REF</b> 82269	Drug F	acts		
ALPHA			<b>redients</b> ine USP 10% w/v % titratable iodine)	<b>Purpose</b> Antiseptic	
<b>I-O-</b>	<b>BEL</b>	<ul> <li>First aid antisep</li> </ul>	th care antiseptic for preparation of the skin prior tic to help reduce bacteria that potentially can cau d professional use		
		Warnings	For External Use Only		
0% POVIDONE	-IODINE GEL		vho are allergic or sensitive to iodine. tiseptic longer than 1 week unless directed by a d	octor.	
	TIC		• <b>before use if you have</b> re wounds, animal bites or serious burns.		
NON-STERILE S			l ask a doctor if	[]	
4 FL OZ (11)	8 mL)	Keep out of	reach of children. If swallowed, get medica Center right away.	l help or contact	
		operative site pr • apply a small a	For preparation of the skin prior to surgery ior to surgery <u>As a first aid antiseptic</u> • clean the mount of this product to the area 1-3 times daily • adage • if bandaged, let dry first	ne affected area	►SS dital Supply, LLC ◎ for AOSS Medical Supply, LLC
		Other Info	<b>FIT TO STORE</b> at room temperature.		<b>Supply,L</b> AOSS MA
			<b>ngredients</b> gen phosphate, Glycerin, Hydroxyethyl cellulose, F	Purified water	Medical
		Questions o	r Comments? Call 800-462-8310		anufac
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LPHA ONE					
vidone-iodine gel					
roduct Information					
roduct Information	HUMAN OTC DRUG	It	em Code (Source)	NDC:53152	-2004

Active Ingredient/Active Moiety					
Ingredient Name	Basis of Strength	Strength			
POVIDONE-IODINE (UNII: 85H0 HZU99M) (IODINE - UNII:9679TC07X4)	IODINE	10 mg in 1 mL			

Inactive Ingredients					
Ingredient Name					
HYDROXYETHYL CELLULOSE (2000 CPS AT 1%) (UNII: S38J6RZN16)					
SO DIUM PHO SPHA	TE, DIBASIC, ANHYDROUS (UNII: 22ADO53M6F)				
WATER (UNII: 059QF0KO0R)					
GLYCERIN (UNII: PI	GLYCERIN (UNII: PDC6A3C0OX)				
Packaging					
# Item Code	Package Description	Marketing Start Date	Marketing End Date		
NDC-ED1ED	110 mI in 1 DOTTLE DI ACTICI Tuna O. Nata Combination				

1 2004-1	Product	OTTLE, PLASTIC; Type 0: NO	t a Compination	10/24/2019		
Marketing Information						
Marketing Cate	gory App	lication Number or Monog	raph Citation	Marketing Start Date	Marketing End Date	
OTC monograph no	t final part33	3A		10/24/2019		

Labeler - AOSS Medical Supply, Inc. (787524651)

Revised: 10/2019

AOSS Medical Supply, Inc.