

**STERILE- povidone-iodine solution**  
**Asia Dynamics Inc., d/b/a ADI Medical**

*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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**Povidone-Iodine Solution, sterile**

***Drug Facts***

***Active ingredient***

Povidone-Iodine USP 10%

***Purpose***

Antiseptic

***Use***

for antiseptic skin preparation

***Warnings***

For external use only

Avoid pooling beneath patient

***do not use***

- if allergic to Iodine
- in the eye

***Stop use and ask a doctor if***

- redness, irritation, swelling or pain persists or increases
- infection occurs

***Keep out of reach of children.***

In case of accidental ingestion, seek professional assistance or consult a poison control center immediately.

***Ask a doctor before use if injuries are***

- deep or puncture wounds
- serious burns

***Directions***

apply locally as needed

**Other information**

- 1% titratable iodine
- for hospital or professional use only

**Inactive ingredients:**

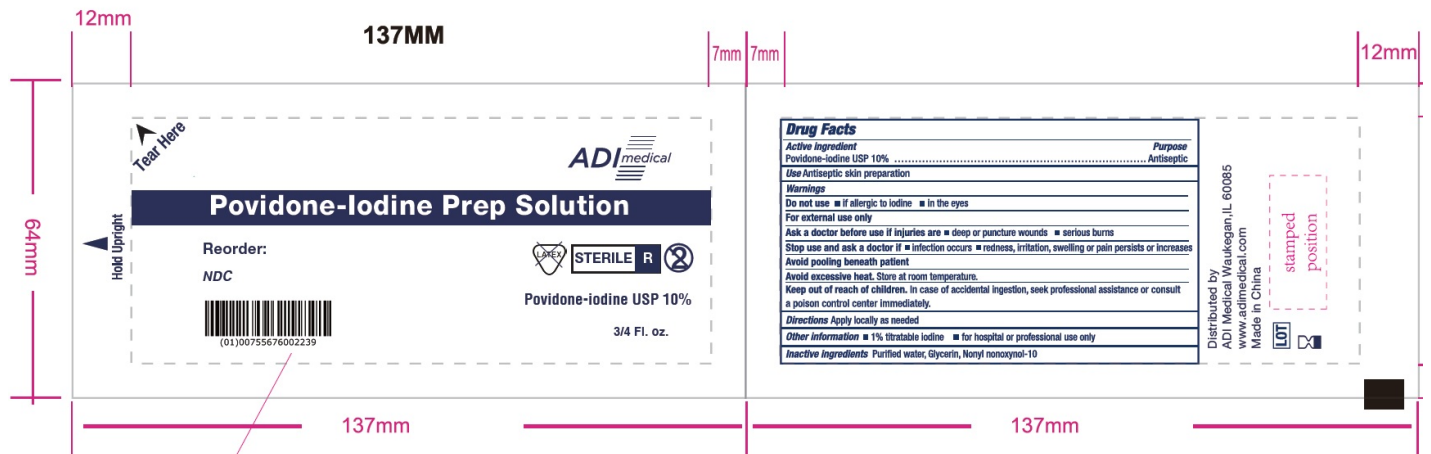
Nonyl Nonoxynol-10, Glycerin, Purified Water.

**Storage**

Avoid excessive heat

Store at room temperature

**Package Labeling:**



NDC 83645-552-11

ADI Medical

<b>STERILE</b>			
povidone-iodine solution			
<b>Product Information</b>			
<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:83645-552
<b>Route of Administration</b>	TOPICAL		
<b>Active Ingredient/Active Moiety</b>			
	<b>Ingredient Name</b>	<b>Basis of Strength</b>	<b>Strength</b>
	<b>POVIDONE-IODINE</b> (UNII: 85H0HZU99M) (IODINE - UNII:9679TC07X4)	IODINE	10 g in 100 g

## Inactive Ingredients

Ingredient Name	Strength
<b>NONOXYNOL-10</b> (UNII: K7O76887AP)	
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	
<b>WATER</b> (UNII: 059QF0KO0R)	

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:83645-552-11	22.5 g in 1 BOTTLE; Type 2: Prefilled Drug Delivery Device/System (syringe, patch, etc.)	09/27/2023	

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333E	09/27/2023	

**Labeler** - Asia Dynamics Inc., d/b/a ADI Medical (607022126)

**Registrant** - Asia Dynamics Inc., d/b/a ADI Medical (607022126)

Revised: 9/2023

Asia Dynamics Inc., d/b/a ADI Medical