

**POVIDONE IODINE- povidone-iodine solution**  
**Qualites t Pharmaceuticals**

*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.*

-----

**POVIDONE IODINE 10% SOLUTION**

***Active ingredient***

Povidone-iodine, 10%  
(1% available iodine)

***Purpose***

First aid antiseptic

***Uses***

first aid to help prevent infection in minor

- cuts
- scrapes
- burns

***Warnings***

**For external use only**

**Do not use**

- in the eyes
- over large areas of the body

**Ask a doctor before use** in case of deep or puncture wounds, animal bites, or serious burns

**Stop use and ask a doctor if**

- the condition persists or gets worse
- you need to use this product for more than 1 week

**Keep out of reach of children.**

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

***Directions***

- clean the affected area
- apply a small amount of product to the area 1 to 3 times daily
- may be covered with a sterile bandage
- if bandaged, let dry first

### Other information

- store at 15° to 30°C (59° to 86°F)

You may report serious side effects to: 130 Vintage Drive, Huntsville, AL 35811.

### Inactive ingredients

citric acid, dibasic sodium phosphate, glycerin, purified water

Manufactured for:

**QUALITEST PHARMACEUTICALS**  
**HUNTSVILLE, AL 35811**

Rev. 2/10 R6  
8071710 1550

### PRINCIPAL DISPLAY PANEL

<p><b>NDC 0603-1550-58</b></p> <p><b>POVIDONE IODINE 10% SOLUTION</b></p> <p>Manufactured for: <b>QUALITEST PHARMACEUTICALS</b> HUNTSVILLE, AL 35811</p> <p>Rev. 2/10 R6 8071710 1550</p> <p><b>non varn</b></p>  <p>N 3 0603-1550-58 4</p>	<p><b>NDC 0603-1550-58</b></p> <p><b>POVIDONE IODINE 10% SOLUTION</b></p> <p><b>TOPICAL ANTISEPTIC</b></p> <p><b>Kills Germs Promptly in Minor Cuts, Scrapes and Burns</b></p> <p><b>NET: 1 PINT (473 mL)</b></p> <p><b>Qualitest®</b></p>	<table border="1"><tr><td colspan="2"><b>Drug Facts</b></td></tr><tr><td><b>Active ingredient</b></td><td><b>Purpose</b></td></tr><tr><td>Povidone-iodine, 10% (1% available iodine) .....</td><td>First aid antiseptic</td></tr><tr><td colspan="2"><b>Uses</b></td></tr><tr><td colspan="2">first aid to help prevent infection in minor</td></tr><tr><td>■ cuts</td><td>■ scrapes</td><td>■ burns</td></tr><tr><td colspan="2"><b>Warnings</b></td></tr><tr><td colspan="2">For external use only</td></tr><tr><td colspan="2"><b>Do not use</b></td></tr><tr><td colspan="2">■ in the eyes</td></tr><tr><td colspan="2">■ over large areas of the body</td></tr><tr><td colspan="2"><b>Ask a doctor before use</b> in case of deep or puncture wounds, animal bites, or serious burns</td></tr><tr><td colspan="2"><b>Stop use and ask a doctor if</b></td></tr><tr><td colspan="2">■ the condition persists or gets worse</td></tr><tr><td colspan="2">■ you need to use this product for more than 1 week</td></tr><tr><td colspan="2"><b>Keep out of reach of children.</b> If swallowed, get medical help or contact a Poison Control Center right away.</td></tr><tr><td colspan="2"><b>Directions</b></td></tr><tr><td colspan="2">■ clean the affected area</td></tr><tr><td colspan="2">■ apply a small amount of product to the area 1 to 3 times daily</td></tr><tr><td colspan="2">■ may be covered with a sterile bandage</td></tr><tr><td colspan="2">■ if bandaged, let dry first</td></tr><tr><td colspan="2"><b>Other information</b></td></tr><tr><td colspan="2">■ store at 15° to 30°C (59° to 86°F)</td></tr><tr><td colspan="2">You may report serious side effects to: 130 Vintage Drive, Huntsville, AL 35811.</td></tr><tr><td colspan="2"><b>Inactive ingredients</b></td></tr><tr><td colspan="2">citric acid, dibasic sodium phosphate, glycerin, purified water</td></tr></table>	<b>Drug Facts</b>		<b>Active ingredient</b>	<b>Purpose</b>	Povidone-iodine, 10% (1% available iodine) .....	First aid antiseptic	<b>Uses</b>		first aid to help prevent infection in minor		■ cuts	■ scrapes	■ burns	<b>Warnings</b>		For external use only		<b>Do not use</b>		■ in the eyes		■ over large areas of the body		<b>Ask a doctor before use</b> in case of deep or puncture wounds, animal bites, or serious burns		<b>Stop use and ask a doctor if</b>		■ the condition persists or gets worse		■ you need to use this product for more than 1 week		<b>Keep out of reach of children.</b> If swallowed, get medical help or contact a Poison Control Center right away.		<b>Directions</b>		■ clean the affected area		■ apply a small amount of product to the area 1 to 3 times daily		■ may be covered with a sterile bandage		■ if bandaged, let dry first		<b>Other information</b>		■ store at 15° to 30°C (59° to 86°F)		You may report serious side effects to: 130 Vintage Drive, Huntsville, AL 35811.		<b>Inactive ingredients</b>		citric acid, dibasic sodium phosphate, glycerin, purified water	
<b>Drug Facts</b>																																																							
<b>Active ingredient</b>	<b>Purpose</b>																																																						
Povidone-iodine, 10% (1% available iodine) .....	First aid antiseptic																																																						
<b>Uses</b>																																																							
first aid to help prevent infection in minor																																																							
■ cuts	■ scrapes	■ burns																																																					
<b>Warnings</b>																																																							
For external use only																																																							
<b>Do not use</b>																																																							
■ in the eyes																																																							
■ over large areas of the body																																																							
<b>Ask a doctor before use</b> in case of deep or puncture wounds, animal bites, or serious burns																																																							
<b>Stop use and ask a doctor if</b>																																																							
■ the condition persists or gets worse																																																							
■ you need to use this product for more than 1 week																																																							
<b>Keep out of reach of children.</b> If swallowed, get medical help or contact a Poison Control Center right away.																																																							
<b>Directions</b>																																																							
■ clean the affected area																																																							
■ apply a small amount of product to the area 1 to 3 times daily																																																							
■ may be covered with a sterile bandage																																																							
■ if bandaged, let dry first																																																							
<b>Other information</b>																																																							
■ store at 15° to 30°C (59° to 86°F)																																																							
You may report serious side effects to: 130 Vintage Drive, Huntsville, AL 35811.																																																							
<b>Inactive ingredients</b>																																																							
citric acid, dibasic sodium phosphate, glycerin, purified water																																																							

### POVIDONE IODINE

povidone iodine solution

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG LABEL	<b>Item Code (Source)</b>	NDC:0603-1550
<b>Route of Administration</b>	TOPICAL	<b>DEA Schedule</b>	

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
POVIDONE-IODINE (IODINE)	POVIDONE-IODINE	100 mg in 1 mL

### Inactive Ingredients

Ingredient Name	Strength
ANHYDROUS CITRIC ACID	
SODIUM PHOSPHATE, DIBASIC	
GLYCERIN	
WATER	

### Product Characteristics

<b>Color</b>	BROWN (dark brown)	<b>Score</b>	
<b>Shape</b>		<b>Size</b>	
<b>Flavor</b>		<b>Imprint Code</b>	
<b>Contains</b>			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0603-1550-56	237 mL in 1 BOTTLE, PLASTIC		
2	NDC:0603-1550-58	473 mL in 1 BOTTLE, PLASTIC		

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH NOT FINAL	part333A	04/01/1995	

**Labeler** - Qualitest Pharmaceuticals (011103059)

### Establishment

Name	Address	ID/FEI	Business Operations
Vintage Pharmaceuticals-Huntsville		825839835	MANUFACTURE(0603-1550)