

## **GRX DYNE - povidone iodine solution**

**Geritrex Corp.**

*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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### **GRx Dyne Solution**

#### **Drug Facts**

Active Ingredient:                      Purpose

Povidone Iodine USP, 10% w/v Antiseptic

(equivalent to 1% titratable Iodine)

#### **Uses**

First aid antiseptic to help the risk of infection in

minor cuts, scrapes or burns

#### **Directions**

Clean the affected area

Apply a small amount of this product to the area 1-3 times daily

May be covered with a sterile bandaged

If bandaged, let dry first

Apply a small amount of this product to the affected area 1-3 times daily

FOR EXTERNAL USE ONLY

DO NOT

Use in the eyes

Use on individuals who are allergic or sensitive to iodine

Apply over large areas of the body

Discontinue use and ask a doctor

If condition persist or gets worse

For use longer than 1 week

Ask a doctor in case of

Deep or punctured wounds

Animal bites

Serious burns

Citric acid, glycerin, Nonoxynol 10, purified water, sodium hydroxide

Store at room temperature: 15'-30'C (59'-86'F)

keep out of reach of children. If swallowed get medical help

or contact a Poison Control Center right away.

PMS 7462



54162-269-04



Povidone Iodine 10% Topical Solution

FOR EXTERNAL USE ONLY

4 FL. OZ. (118ml)

<b>Drug Facts</b>	
<b>Active Ingredient:</b> . . . . . Povidone Iodine USP, 10% w/v (equivalent to 1% titratable Iodine)	<b>Purpose</b> Antiseptic
<b>Use:</b> First aid antiseptic to help prevent the risk of infection in minor cuts, scrapes or burns	
<b>Warnings:</b> <b>FOR EXTERNAL USE ONLY.</b>	
<b>DO NOT</b>	
<ul style="list-style-type: none"> <li>• Use in the eyes</li> <li>• Use on individuals who are allergic or sensitive to iodine</li> <li>• Apply over large areas of the body</li> </ul>	
<b>Discontinue use and ask a doctor</b>	
<ul style="list-style-type: none"> <li>• If condition persist or gets worse</li> <li>• For use longer than 1 week</li> </ul>	
<b>Ask a doctor in case of</b>	
<ul style="list-style-type: none"> <li>• Deep or punctured wounds</li> <li>• Animal bites</li> <li>• Serious burns</li> </ul>	
<b>Keep out of reach of children.</b> If swallowed get medical help or contact a Poison Control Center right away.	
<b>Directions:</b>	
<ul style="list-style-type: none"> <li>• Clean the affected area</li> <li>• Apply a small amount of this product to the area 1-3 times daily</li> <li>• May be covered with a sterile bandaged</li> <li>• If bandaged, let dry first</li> </ul>	
<b>Other information:</b>	
Store at room temperature: 15°-30°C (59°-86°F)	
<b>Inactive Ingredients:</b> Citric Acid, glycerin, Nonoxynol 10, purified water, sodium hydroxide	

Geritrex Corporation  
144 Kingsbridge Road East  
Mount Vernon, NY 10550  
1-800-736-3437  
www.geritrex.com



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<b>GRX DYNE</b>			
povidone iodine solution			
<b>Product Information</b>			
<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:54162-269
<b>Route of Administration</b>	TOPICAL		
<b>Active Ingredient/Active Moiety</b>			
	<b>Ingredient Name</b>	<b>Basis of Strength</b>	<b>Strength</b>

POVIDONE-IODINE (UNII: 85H0HZU99M) (POVIDONE-IODINE - UNII:85H0HZU99M)	POVIDONE-IODINE	10 mL in 100 mL
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### Inactive Ingredients

Ingredient Name	Strength
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
GLYCERIN (UNII: PDC6A3C0OX)	
NONOXYNOL-10 (UNII: K7O76887AP)	
WATER (UNII: 059QF0KO0R)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:54162-269-04	118 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	05/21/2012	

**Labeler** - Geritrex Corp. (112796248)

Revised: 5/2012

Geritrex Corp.