

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.

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

Warnings

FOR EXTERNAL USE ONLY
DO NOT
Use in the eyes
Use on individuals who are allergic of 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

Inactive Ingredient

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.



54162-269-16



Povidone Iodine 10% Topical Solution

FOR EXTERNAL USE ONLY

16 FL. OZ. (472mL)

Drug Facts	
Active Ingredient: Povidone Iodine USP, 10% w/v (equivalent to 1% titratable iodine)	Purpose: Antiseptic
Use: First aid antiseptic to help prevent the risk of infection in minor cuts, scrapes or burns	
Warnings: FOR EXTERNAL USE ONLY.	
DO NOT	
<ul style="list-style-type: none"> 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	
<ul style="list-style-type: none"> If condition persist or gets worse For use longer than 1 week 	
Ask a doctor in case of	
<ul style="list-style-type: none"> Deep or punctured wounds Animal bites Serious burns 	
Keep out of reach of children. If swallowed get medical help or contact a Poison Control Center right away.	
Directions:	
<ul style="list-style-type: none"> 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 	
Other Information:	
Store at room temperature: 15°-30°C (59°-86°F)	
Inactive Ingredients: 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

811



Enter section text here

GRX DYNE

povidone iodine solution

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:54162-269
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
POVIDONE-IODINE (UNII: 85H0HZU99M) (POVIDONE-IODINE - UNII:85H0HZU99M)	POVIDONE-IODINE	10 mL in 100 mL

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:54162-269-16	472 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	05/16/2012	

Labeler - Geritrex Corp. (112796248)

Revised: 5/2012

Geritrex Corp.