GYNO-BETADINE- povidone iodine solution OASIS TRADING

Disclaimer: This drug has not been found by FDA to be safe and effective, and this labeling has not been approved by FDA. For further information about unapproved drugs, click here.

POVIDONE-IODINE

Local treatment in the following cases: Candidate vaginitis, trichomonas vaginitis, non-specific and mixed infection, preoperative pre-operative treatment of obstetrics and gynecology, local cleaning and release

Keep out of reach of children

Dilute 30 ml of water in about 1 liter of hot water and wash the inside and outside of vagina once or twice a day. Clean sterilizable vaginal cleaning, local cleaning, and deodorization once or twice a week.

Do not use

in the eyes as a first aid antiseptic longer than one week on individuals who are allergic or sensitive to iodine over large areas of the body

Keep out of reach of children.

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

Water, etc.

For vaginal use only

GYNO-BETADINE (VAGINAL WASH)

Drug Facts

Active Ingredients (in 1g) Purpose
Policresulen Solution 720mg ----- Antiseptic

Uses

■ Local treatment in the following cases: Candidate vaginitis, trichomonas vaginitis, non-specific and mixed infection, preoperative pre-operative treatment of obstetrics and gynecology, local cleaning and release

Warnings

For vaginal use only.

Do not use in the eyes by putting this product into the rectum by using fingers or any mechanical device or applicator.

Ask a doctor before use if you have a vaginal discharge, rectal bleeding, diaper rash.

When using this product consult a doctor before exceeding recommended dosage.

Stop use and ask a doctor if condition gets worse, condition persists for more than 7 days, condition clears up and occurs again with within a few days. Do not begin to use any other hydrocortisone product unless you have consulted a doctor.

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

Directions

■ Dilute 30 ml of water in about 1 liter of hot water and wash the inside and outside of vagina once or twice a day. Clean sterilizable vaginal cleaning, local cleaning, and deodorization once or twice a week.

Other Information

■ Store at controlled room temperature 20-25 degrees C (68-77 degrees F).

Inactive Ingredient

Water

Questions or comments?

Call weekdays from 9 a.m to 5 p.m EST at (201) 669-8405 Distributed By: P&K FRONTIER MARKETING CORP.

329 BROAD AVENUE # 2F, PALISADES PARK, NJ 07650, USA

Made in South Korea

GYNO-BETADINE

povidone iodine solution

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H	ro	a	uct	Into	rmation

Product Type HUMAN OTC DRUG Item Code (Source) NDC:72689-0041

Route of Administration VAGINAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
PO VIDO NE-IO DINE (UNII: 85H0 HZU99 M) (IO DINE - UNII:9679 TC07X4)	IODINE	10 g in 100 mL

	Inactive	Ingredients
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Ingredient Name	Strength

WATER (UNII: 059QF0KO0R)					
Packaging					
# Item Code	Package Description	Marketing Start Date Marketing End Date			

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
unapproved drug other		11/21/2018		

1 NDC:72689-0041-1 180 mL in 1 BOTTLE; Type 0: Not a Combination Product 11/21/2018

Labeler - OASIS TRADING (689991468)

Registrant - OASIS TRADING (689991468)

Establishment			
Name	Address	ID/FEI	Business Operations
OASIS TRADING		689991468	manufacture(72689-0041), relabel(72689-0041)

Revised: 3/2019 OASIS TRADING