

GYNO-BETADINE- povidone iodine suppository
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

Put 200 mg deep into the vagina once a day. It is advisable to insert it in the evening before bedtime. To increase or decrease appropriately according to age and symptoms.

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.

POLYETHYLENE GLYCOL 1540

For vaginal use only

GYNO-BETADINE (VAGINAL SUPPOSITORIES)

Drug Facts	
Active Ingredients (in 1 suppository) Povidone Iodine 200mg -----	Purpose Antiseptic
Uses <ul style="list-style-type: none"> 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 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.	
Directions <ul style="list-style-type: none"> Put 200 mg deep into the vagina once a day. It is advisable to insert it in the evening before bedtime. To increase or decrease appropriately according to age and symptoms. 	
Other Information <ul style="list-style-type: none"> Store at controlled room temperature 20-25 degrees C (68-77 degrees F). 	
Inactive Ingredient Polyethylen Glycol 1540	
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 suppository

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:72689-0042
Route of Administration	VAGINAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
POVIDONE-IODINE (UNII: 85H0HZU99M) (IODINE - UNII:9679TC07X4)	IODINE	200 mg

Inactive Ingredients

Ingredient Name	Strength
POLYETHYLENE GLYCOL 1500 (UNII: 1212Z7S33A)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:72689-0042-1	10 in 1 BLISTER PACK; Type 0: Not a Combination Product	11/21/2018	

Marketing Information

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

Labeler - OASIS TRADING (689991468)

Registrant - OASIS TRADING (689991468)

Establishment

Name	Address	ID/FEI	Business Operations
OASIS TRADING		689991468	manufacture(72689-0042) , relabel(72689-0042)

Revised: 3/2019

OASIS TRADING