

BELLA FLORE- povidone-iodine
Natureplex LLC

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.

Bella Flore
Medicated Douche

Drug Facts

Active ingredient (in each bottle when mixed with packet)

Povidone-iodine 0.3%

Purpose

Antimicrobial

Use

for temporary relief of minor vaginal irritation or itching

Warnings

For vaginal use only

Do not use

- if you have an iodine sensitivity
- to prevent pregnancy
- if you are trying to become pregnant or during pregnancy
- if you have symptoms of pelvic inflammatory disease (PID), such as lower abdominal pain, fever, chills, nausea, vomiting, and/or a pus-like yellow cervical discharge; see a doctor right away
- if you have symptoms of sexually transmitted
- diseases (STD), such as vaginal discharge of an unusual amount, color, or odor, painful and/or frequent urination, genital sores or ulcers; see a doctor right away to self-treat or prevent an STD or PID after exposure to an STD

Stop use and ask a doctor if

- douching results in pain, soreness, swelling, redness, itching, excessive dryness, or irritation
- symptoms continue after 7 days

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

Directions

Preparing the douche

- remove sanitary overwrap and unscrew nozzle cap
- carefully open the medicated packet and pour into the douche bottle. The contents can stain certain materials.
- screw the nozzle cap back onto the bottle

- swirl bottle *gently* to mix
- after mixing, use within one hour

When and how to douche

- use once daily for seven days, even if symptoms disappear sooner
- gently insert nozzle into vagina, no more than 3 inches, and slowly squeeze bottle
- *do not close the vaginal opening*; douching solution should flow freely out of vagina
- use while sitting on the toilet, in the tub, or while standing in the shower

Other information

- an association has been reported between douching and pelvic inflammatory disease (PID), ectopic pregnancy, and infertility. It is not currently known whether douching is causally related to these conditions, but women should be aware of this association.
- see a doctor right away if you have symptoms of PID or STD
- bottle and douche concentrate packet sealed for your protection. Do not use if seal under cap is torn or missing, or packet is leaking.

Inactive ingredients

citric acid, edetate disodium, purified water, sodium benzoate, sodium lauryl sulfate, trisodium phosphate

Questions?

1-866-323-0107

PRINCIPAL DISPLAY PANEL - 133 mL Kit Carton

bella flore

douche

medicated

pH-Balanced

Relieves Minor

Vaginal Irritation
& Itching

*Compare To

Summer's Eve®

2

Two Unit

4.5 fl. oz.(133mL)

Do not use if protective lid seal is broken or missing.
Tamper Resistant

IMPORTANT:
READ ALL
INSTRUCTIONS
BEFORE USING
THIS PRODUCT

bella  flore
douche

bella  flore
douche

bella  flore
douche

bella  flore
douche



medicated

Carefully open the medicated packet (do this carefully as the povidone-iodine can stain certain materials) and pour into the douche bottle. Replace nozzle cap, swirl and the douche is ready for use.



medicated

pH-Balanced
Relieves Minor
Vaginal Irritation
& Itching



medicated

Bella Flore Medicated Douche contains Povidone-Iodine, the ingredient doctors recommend, for relief of minor vaginal irritation and itching. The mild, yet effective, pH-balanced formula has been gynecologist tested for gentleness to make sure you're getting the proper attention without irritation. Plus the comfort slant bottle is easy and comfortable to use.

* This product is not manufactured or distributed by Personid Laboratories, a Division of C.B. Fleece Co., Lynchburg, VA 24502, U.S.A., owner of the registered trademark Summer's Eve®.

*Compare To
Summer's Eve®

2
Two Units
4.5 fl. oz. (133ml) Each



Comfort
Slant
Bottle

Natureplex

MADE IN THE USA



bellaflore

douche

Drug Facts

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Povidone-iodine 0.3%	Antimicrobial

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- to self-treat or prevent an STD or PID
- after exposure to an STD

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Questions? 1-866-323-0107

NDC# 67234-022-01





BELLA FLORE

povidone-iodine kit

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:67234-022
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Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:67234-022-01	1 in 1 CARTON	01/02/2012	
2	NDC:67234-022-02	1 in 1 CARTON	01/02/2012	

Quantity of Parts

Part #	Package Quantity	Total Product Quantity
Part 1	1 PACKET	8 mL
Part 2	2 BOTTLE, WITH APPLICATOR	266 mL

Part 1 of 2

POVIDONE-IODINE

povidone-iodine douche

Product Information

Route of Administration	VAGINAL
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Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
POVIDONE-IODINE (UNII: 85H0HZU99M) (IODINE - UNII:9679TC07X4)	IODINE	0.3 g in 100 mL

Inactive Ingredients

Ingredient Name	Strength
EDETATE DISODIUM (UNII: 7FLD91C86K)	
COCO DIETHANOLAMIDE (UNII: 92005F972D)	

SODIUM BENZOATE (UNII: OJ245FE5EU)	
SODIUM LAURETH-3 SULFATE (UNII: BPV390UAP0)	
SODIUM PHOSPHATE, TRIBASIC (UNII: A752Q30A6X)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
WATER (UNII: 059QF0KO0R)	
COCAMIDOPROPYL BETAINE (UNII: 5OCF3011KX)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		8 mL in 1 PACKET; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	01/02/2012	

Part 2 of 2

BELLA FLORE

douches solution

Product Information

Route of Administration	VAGINAL
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Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		133 mL in 1 BOTTLE, WITH APPLICATOR; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
Cosmetic		01/02/2012	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	01/02/2012	

Labeler - Natureplex LLC (062808196)

Establishment

Name	Address	ID/FEI	Business Operations
Natureplex LLC		062808196	MANUFACTURE(67234-022)

Revised: 2/2021

Natureplex LLC