SUMMERS EVE- povidone-iodine douche
C.B. Fleet Company, Inc.

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.

Summers Eve povidone-iodine 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 the reach of children.

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

Directions

Preparing to douche:

- remove sanitary overwrap and unscrew nozzle cap
- hold and squeeze foil packet just below notch. Tear off at notch. Carefully insert tip into douche bottle. The contents can stain certain materials.

- screw the nozzle cap back onto the bottle
- swirl bottle gently to mix. Hold cap of bottle with one hand and grasp Comfortip® nozzle firmly with the other hand.

- *pull nozzle straight up until it clicks in place*. Douche is not ready for use until you hear this click.
- after mixing, use within one hour

When and how to douche:
- use once daily for up to three days
- *gently* insert nozzle into your 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 overwrapped and douche concentrate packet sealed for your protection. Do not use if overwrap imprinted "FRESHNESS HAS NEVER BEEN SIMPLER" is torn or missing, or packet is leaking.

Inactive ingredients

citric acid, edetate disodium, phosphoric acid*purified water, sodium benzoate, sodium hydroxide, sodium lauryl sulfate, sodium phosphate tribasic

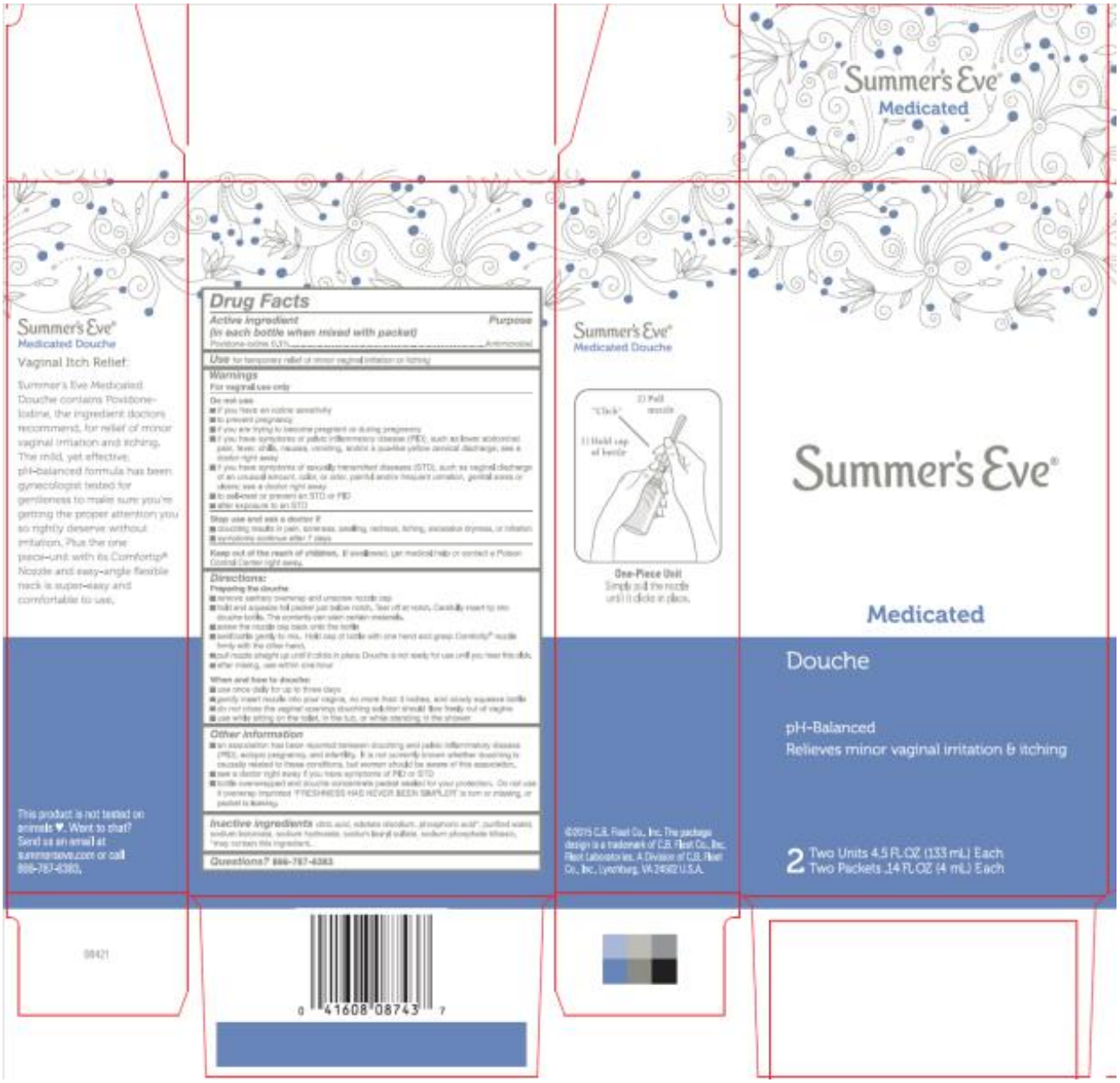
*may contain this ingredient

Questions?

1-866-787-6383

PRINCIPAL DISPLAY PANEL

Summer’s Eve
Medicated
Douche



SUMMERS EVE

povidone-iodine douche

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:0132-8743
Route of Administration	VAGINAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
POVIDONE-IODINE (UNII: 85H0HZU99M) (IODINE - UNII:9679TC07X4)	IODINE	4 g in 133 mL

Inactive Ingredients	
Ingredient Name	**Strength**

PHOSPHORIC ACID (UNII: E4GA8884NN)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
WATER (UNII: 059QF0KO0R)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
SODIUM PHOSPHATE, TRIBASIC, ANHYDROUS (UNII: SX01TZO3QZ)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0132-8743-02	133 mL in 1 BOTTLE; Type 0: Not a Combination Product	05/10/2002	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH NOT FINAL	part333E	05/10/2002	

Labeler - C.B. Fleet Company, Inc. (003119054)

Revised: 7/2020 C.B. Fleet Company, Inc.