

GUARDIAN VAGINAL- benzalkonium chloride douche

Eastern Century Pharmaceuticals

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.

Eastern Century - Guardian Gel Vaginal Douche

Active ingredient

Benzalkonium Chloride 0.1%

Purpose

antimicrobial

Uses:

- for vaginal cleansing. Kills germs.

Warnings:

Wash and douche with water. Do not Douche to prevent pregnancy. During pregnancy. If you have symptoms of pelvic inflammatory disease (PID) or a sexually transmitted disease (STD). To self-treat or prevent a STD or PID. After exposure to a STD Stop using this product stop using this product and consult a doctor if douching results in pain, soreness, swelling, redness, itching excessive dryness or irritation, or symptoms continue after 7 days. These may indicate serious condition. If swallowed, get medical help or contact a Poison Control Center right away.

External use only.

Do not use in eyes.

Stop use and ask a doctor if:

Rash and irritation and redness develops.

Discontinue use if

any burning, itching, or irritation of the vagina occur during use.

Keep out of reach of children.

Directions:

Insert the gel into the vagina when cleansing is desired, one unit (5.5ml) each time.

Please read the following instructions carefully before use.

1. Take off any plastic around the tube.
2. Remove the small plastic tip from the top of the applicator.
3. Gently insert the small end of the applicator deep into the vagina. While in this position, squeeze the entire contents of the applicator to release the gel. Remove the applicator and discard it in a waste container.

- Do not use this product if the package seal is broken.
- Children under 12 years of age: ask doctor.

Inactive ingredients:

Carbomer, Glycerin, Hydroxypropylmethylcellulose, Methylparaben, Sodium Hydroxide, Water

Storage:

Store at room temperature in a cool, dry place.

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 casually 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.

Expiration Date:

Two years after printed date of manufacture.

Precautions:

Discontinue use if any burning, itching, or irritation of the vagina occurs during use. Wash and douche with water. Guardian Gel TM is an effective douche when used according to the directions.

Distributed by:

Eastern Century Pharmaceuticals, US (ECP)
One Pierce Place, #475W, Itasca, IL 60143 USA
Made in the USA

Front Label

Guardian Gel

Vaginal Douche Gel with Benzalkonium Chloride

0.18 fl oz. 5.5 ml



Back Label

DRUG FACTS

Active Ingredients

Benzalkonium Chloride 0.1%.....antimicrobial

Purpose:

USES: ■ For vaginal cleansing. Kills germs.

WARNINGS: ■ Stop use and ask a doctor if: Rash or irritation develops. ■ Discontinue use if any burning, itching or irritation of the vagina occur during use. Wash and douche with water. ■ Do not douche to prevent pregnancy. ■ During pregnancy ■ If you have symptoms of pelvic inflammatory disease (PID) or a sexually transmitted disease (STD). ■ To self-treat or prevent a STD or PID ■ After exposure to a STD stop using this product and consult a doctor if douching results in pain, soreness, swelling, redness, itching, excessive dryness or irritation, or symptoms continue after 7 days. These may indicate a serious condition. ■ If swallowed, get medical help or contact a Poison Control Center right away. ■ External use only ■ Do not use in the eyes ■ **KEEP OUT OF REACH OF CHILDREN.**

DIRECTIONS: Insert the gel into the vagina when cleansing is desired, one unit (5.5 ml) each time. Please read the following instructions carefully before use:

1. Take off any plastic around the tube.
 2. Remove the small plastic tip from the top of the applicator.
 3. Gently insert the small end of the applicator deep into the vagina. While in this position, squeeze the entire contents of the applicator to release the gel. Remove the applicator and discard it in a waste container.
- Do not use this product if the package seal is broken.
■ Children under 12 years of age: ask doctor.

Inactive Ingredients: Carbomer, Glycerin, Hydroxypropylmethylcellulose, Methylparaben, Sodium Hydroxide, Water.

OTHER:

Storage: Store at room temperature in a cool, dry place.

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 casually related to these conditions, but women should be aware of the association. ■ See a doctor right away if you have symptoms of PID or STD.

Expiration date: Two years after printed date of manufacture. **Precautions:** Discontinue use if any burning, itching, or irritation of the vagina occurs during use. Wash and douche with water. **Guardian Gel™** is an effective douche when used according to directions.

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One Pierce Place, #475W, Itasca, IL 60143 USA Made in the USA.

GUARDIAN VAGINAL

benzalkonium chloride douche

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:68915-280
Route of Administration	VAGINAL		

Active Ingredient/Active Moiety

Ingredient Name		Basis of Strength	Strength	
BENZALKONIUM CHLORIDE (UNII: F5UM2KM3W7) (BENZALKONIUM - UNII:7N6JUD5X6Y)		BENZALKONIUM CHLORIDE	1 mg in 1 mL	
Inactive Ingredients				
Ingredient Name			Strength	
CARBOMER 934 (UNII: Z135WT9208)				
GLYCERIN (UNII: PDC6A3C0OX)				
HYPROMELLOSES (UNII: 3NXW29V3WO)				
METHYL PARABEN (UNII: A2I8C7HI9T)				
SODIUM HYDROXIDE (UNII: 55X04QC32I)				
WATER (UNII: 059QF0K00R)				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:68915-280-02	1 in 1 BOX	05/23/2011	
1	NDC:68915-280-01	5.5 mL in 1 BOTTLE; 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	05/23/2011	

Labeler - Eastern Century Pharmaceuticals (966499373)

Registrant - Eastern Century Pharmaceuticals (966499373)

Establishment

Name	Address	ID/FEI	Business Operations
Woodbine Products Company		004220323	manufacture(68915-280)

Revised: 9/2019

Eastern Century Pharmaceuticals