

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.

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™ is an effective douche when used according to the directions.

Distributed by:

Eastern Century Pharmaceuticals, US (ECP)
2345 Oakwood Dr., Prescott, AZ 86305 USA
Made in the USA

Front Label

Guardian Gel

Vaginal Douche Gel with Benzalkonium Chloride

0.18 fl oz. 5.5 ml

GUARDIAN GEL™

Vaginal Douche Gel with
Benzalkonium Chloride

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GUARDIAN GEL™

Vaginal Antiseptic and Antimicrobial Gel
For daily hygiene, cleansing and protection.
Patents pending.

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Back Label

Drug Facts

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Uses: ■ for vaginal cleansing. Kills germs.

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■ Stop use and ask a doctor if: Rash or irritation and redness 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.

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GUARDIAN GEL™

Vaginal Douche Gel with
Benzalkonium Chloride

GUARDIAN VAGINAL

benzalkonium chloride douche

Product Information

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

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
BENZALKONIUM CHLORIDE (BENZALKONIUM)	BENZALKONIUM CHLORIDE	1 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
CARBOMER 934	
GLYCERIN	
HYPROMELLOSES	
METHYL PARABEN	
SODIUM HYDROXIDE	
WATER	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:68915-280-02	1 in 1 BOX		
1	NDC:68915-280-01	5.5 mL in 1 BOTTLE		

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
Lifetech Resources, LLC		622559110	manufacture(68915-280)