

AVVA- benzalkonium chloride gel
AVVA International 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.

Drug Facts

Active ingredients

Benzalkonium Chloride 0.1%

Purpose

Antimicrobial

Keep out of reach of children if product is swallowed, get medical help or contact a poison control center right away

Uses: for vaginal cleansing. Kills germs.

Directions:

- take of any plastic around the tube
- remove the small plastic cap from the top of the applicator
- gently insert the end with small hole of the applicator deep into the vagina, while in this position gently push the plunger of the applicator to release the gel
- remove the applicator and discard it in a waste container
- children under 12 years of age: Ask a doctor

Do not use if the package seal is broken

Warnings:

For external use only

Do not use

- more often than twice weekly unless directed by physician
- to prevent pregnancy
- during pregnancy
- if you have symptoms of pelvic inflammatory disease (PID) or sexually transmitted disease (STD)
- to prevent STD or PID

When using this product keep out of eyes. Rinse with water to remove

Stop use and ask doctor if rash, irritation, swelling, pain or redness develops

Do not use more often than twice weekly unless directed by physician

Inactive Ingredients:

allantoin, carbomer, glycerin, hydroxyethylcellulose, sodium hydroxide, water



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Other Information: <ul style="list-style-type: none"> • do not use if the package seal is broken • store at room temperature in a cool dry place • 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 woman should be aware of this association 	
Inactive Ingredients: allantoin, carbomer, glycerin, hydroxyethylcellulose, sodium hydroxide, water	
Questions or comments? call 1-407-992-8178 or visit www.avvagel.com	

Distributed by:
AVVA International LLC
 37 North Orange Ave., Suite 500, Orlando, FL 32801, USA
 Made in the USA

AVVA
 Vaginal Douche Gel with
 Benzalkonium Chloride

Expiration Date:
Lot/Control No.:

AVVA

benzalkonium chloride gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:42891-4148
Route of Administration	VAGINAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
BENZALKONIUM CHLORIDE (UNII: F5UM2KM3W7) (BENZALKONIUM - UNII: 7N6JUD5X6Y)	BENZALKONIUM CHLORIDE	100 mg in 100 mL

Inactive Ingredients

Ingredient Name	Strength
ALLANTOIN (UNII: 344S277G0Z)	
CARBOMER HOMOPOLYMER TYPE B (ALLYL SUCROSE CROSSLINKED) (UNII: Z135WT9208)	
GLYCERIN (UNII: PDC6A3C0OX)	
HYDROXYETHYL CELLULOSE (4000 MPA.S AT 1%) (UNII: ZYD53NBL45)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	

WATER (UNII: 059QF0KO0R)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:42891-4148-0	6 in 1 BOX	03/28/2012	
1	NDC:42891-4148-1	5.5 mL in 1 TUBE; 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	03/28/2012	

Labeler - AVVA International LLC (020023853)

Revised: 1/2022

AVVA International LLC