

# **FEMALE INTIMATE HYGIENE ANTIBACTERIAL GELS- benzalkonium bromide gel ShenZhen MengTi Biotechnology Co.Ltd**

*Disclaimer: This drug has not been found by FDA to be safe and effective, and this labeling has not been approved by FDA. For further information about unapproved drugs, click here.*

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## **Female Intimate Hygiene Antibacterial Gels**

Female Intimate Hygiene Antibacterial Gels

### **Active Ingredient(s)**

Benzalkonium bromide 0.10% w/w. Purpose: Antibiotic

### **Purpose**

Antibiotic, Female Intimate Hygiene Antibacterial Gels

### **Use**

for vagina to inhibit Staphylococcus aureus, Escherichia coli and Candida albicans. This product is not a substitute for medicines.

### **Warnings**

For external use only  
Disposable, do not reuse it

### **Do not use**

- during menstruation, pregnancy, or breastfeeding

do not get into eyes  
if contact occurs, rinse eyes thoroughly with water

Stop use and ask a doctor if irritation or rash occurs. These may be signs of a serious condition.

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

### **Directions**

- Wash hands and clean the vulva
- Remove the front cover of the gel and insert the removed front cover into the rear end of the gel tube as a push rod
- Lie on your back and push the gel into the vagina with the gel pusher
- Take out the gel pusher, and lie still for three minutes.

## Other information

- Store between 15-30C (59-86F)
- Avoid freezing and excessive heat above 40C (104F)

## Inactive ingredients

Sophora Flavescens Root Extract, Averrhoa Carambola Fruit Extract, Glycine Max (Soybean) Seed Extract, Pyrus Pyrifolia Fruit Extract

## Package Label - Principal Display Panel



## FEMALE INTIMATE HYGIENE ANTIBACTERIAL GELS

benzalkonium bromide gel

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:81983-101
<b>Route of Administration</b>	TOPICAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>BENZALKONIUM BROMIDE</b> (UNII: 151T1GQ42D) (BENZALKONIUM - UNII: 7N6JUD5X6Y)	BENZALKONIUM BROMIDE	0.1 g in 100 g

## Inactive Ingredients

Ingredient Name	Strength
<b>NASHIPATI</b> (UNII: SHY4TJD066)	
<b>SOPHORA FLAVESCENS WHOLE</b> (UNII: X8KX602M5L)	
<b>STAR FRUIT</b> (UNII: G00N2E9394)	
<b>SOYBEAN</b> (UNII: L7HT8F1ZOD)	

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:81983-101-02	10 in 1 BOX	06/08/2021	
1	NDC:81983-101-01	3.5 g in 1 BAG; Type 0: Not a Combination Product		

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		06/08/2021	

**Labeler** - ShenZhen MengTi Biotechnology Co.Ltd (705839690)

## Establishment

Name	Address	ID/FEI	Business Operations
Yunnan Baifeng Pharmaceutical Co. Ltd		731098614	manufacture(81983-101)

Revised: 6/2021

ShenZhen MengTi Biotechnology Co.Ltd