

BETAFEM®

BV GEL

Instructions for Use

Important Information

Please read and understand the information provided in this leaflet carefully and keep it in case you need to refer to it again.

What is BETAFEM® BV Gel?

- Treats bacterial vaginosis (BV)
- Prevents recurrent BV
- Provides rapid relief of vaginal discomforts such as unpleasant odour and discharge
- Restores normal vaginal flora balance
- Well tolerated as is not absorbed into the blood stream

BETAFEM® BV Gel, which contains astodimer sodium 10mg/g (1%), a patented dendrimer, works by creating a physical barrier that targets the BV-causing bad bacteria. This barrier prevents the bad bacteria from attaching to the vaginal lining, reducing its opportunity to grow whilst allowing the good bacteria to replenish, helping to normalise the vaginal pH, and relieves unpleasant odour and discharge. This product is not an antibiotic.

BETAFEM® BV Gel is not absorbed into the body following vaginal application.

BETAFEM® BV Gel also contains purified water, carbomer homopolymer type A, sodium hydroxide, glycerin, propylene glycol, methyl p-hydroxybenzoate, propyl p-hydroxybenzoate and edetate disodium dihydrate.

What is Bacterial Vaginosis?

Bacterial Vaginosis, also known as BV, is an imbalance in the naturally occurring vaginal bacteria and is associated with symptoms including a strong 'fishy' vaginal odour, which can be worse after sex, and an abnormal greyish-white, thin vaginal discharge, which can cause discomfort. BV can have a high rate of recurrence in some women.

When should BETAFEM® BV Gel be used?

BETAFEM® BV Gel is a clear gel intended to be applied into the vagina and has been clinically tested and shown to:

- Treat BV, restore vaginal flora balance, and normalise vaginal pH.
- Provide rapid resolution of symptoms including fishy vaginal odour and discharge.
- Prevent recurrent BV and its symptoms.

How do I use BETAFEM® BV Gel?

For vaginal use only.

Treatment

One applicator full (5g), applied vaginally once daily, preferably at bedtime, for 7 days. It is important to complete all 7 applications, even if your symptoms go away.

Prevention

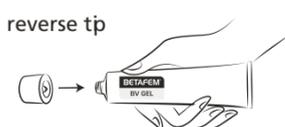
One applicator full (5g), applied vaginally once every second day, preferably at bedtime.

BETAFEM® BV Gel can be used when you are having your period. It is recommended to apply BETAFEM® BV Gel after any sexual activity if you are using the product at bedtime.

Directions for the multi-dose tube and disposable applicator

A single dose of BETAFEM® BV Gel (5g) is to be filled into the applicator. Follow the steps below to prepare the applicator for use:

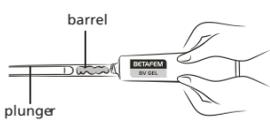
1. Remove cap from tube and puncture metal seal on tube with the pointed tip of cap.



2. Remove one applicator from the wrapper and screw the threaded end onto the tube.



3. Slowly squeeze the tube from the bottom to fill the applicator with gel until the plunger stops moving. The applicator now contains the correct amount of gel.



4. Once filled, unscrew the applicator from the tube and replace the tube cap. The filled applicator is now ready to be used.

5. In a sitting or standing position, hold the applicator barrel between the thumb and middle finger, and gently insert the applicator as far as comfortably possible into the vagina.



6. Hold the applicator in place and slowly push the plunger until it stops dispersing the gel into the vagina.

7. Carefully remove the applicator, keeping the plunger depressed.

8. Dispose of the used tube and applicator responsibly into a waste container. Do not flush into the toilet.

Warnings and Precautions

See your doctor or pharmacist if:

- You consider that you may be at risk of a Sexually Transmitted Infection (STI);
- Your symptoms persist or recur, or your condition worsens;
- Irritation occurs following use of the product;
- You are pregnant or plan to become pregnant or you are breastfeeding or plan to breastfeed.

Do not use BETAFEM® BV Gel

- In girls before the onset of puberty
- If you have a history of sensitivity to astodimer sodium, hydroxybenzoates or any other ingredients in the formulation
- If the applicator wrapper is not present or torn, or if the metal tube seal has been punctured.

Do not share your applicator with anyone. Dispose of the applicator responsibly after completing all doses.

Will BETAFEM® BV Gel interfere with any other products or medicines?

BETAFEM® BV Gel is not expected to interfere with medications because astodimer sodium in the product is not absorbed into the bloodstream following vaginal application.

Due to incompatibility, use of other vaginal products containing polyquaterniums, which are found in some personal lubricants, should be avoided while using BETAFEM® BV Gel.

BETAFEM® BV Gel can be used with condoms; however, it is recommended to apply BETAFEM® BV Gel after any sexual activity if you are using the product at bedtime.

Are there any side effects of BETAFEM® BV Gel?

The majority of women will likely not experience side effects. However a small percentage reported headache, itching or burning around the vaginal area, abdominal pain, urinary tract infection and yeast infection.

Storage

Store BETAFEM® BV Gel below 30°C.

Do not refrigerate or freeze.

Keep out of reach of children.

See bottom of carton and bottom of tube for lot number and expiry date.

Disposal

 Dispose responsibly into waste container. Do not flush into the toilet.

What does the package contain?

The carton contains:

- one sealed multi-dose aluminium tube containing 40 grams of BETAFEM® BV Gel, sufficient for seven doses
- seven single use disposable measured dose vaginal applicators
- one instruction for use

Manufacturer


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EC Representative

EC REP

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