

Consumer Medicine Information

Instructions for Use

For use by females of all ages, after the onset of puberty.

Important Information

Prior to use, note the following:

- Read carefully, understand and follow the information provided in this leaflet.
- Use the product only as directed.
- Keep this leaflet in case you need to read it again.
- Please see a healthcare professional for diagnosis of BV.

What is Fleurstat BVgel?

Fleurstat BVgel is a clear gel intended to be applied into the vagina for the treatment of bacterial vaginosis (or BV) and relief of symptoms, including abnormal vaginal odour and discharge, helping to normalise vaginal pH and restore the normal vaginal flora balance.

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.

The exact cause of the bacterial imbalance, characterised by overgrowth of naturally occurring but objectionable bacteria, and loss of beneficial bacteria, is unknown.

Fleurstat BVgel contains astodimer sodium (VivaGel®, active ingredient) at a concentration of 10 mg/g (1% w/w) in a gel consisting of purified water, carbomer homopolymer type A, sodium hydroxide, glycerol, propylene glycol, methyl hydroxybenzoate and propyl hydroxybenzoate (preservatives) and disodium edetate. Fleurstat BVgel has a pH that is similar to normal vaginal pH.

How does Fleurstat BVgel work?

Fleurstat BVgel is for the treatment of BV and relief of symptoms, including abnormal vaginal odour and discharge, helping to normalise vaginal pH, and restore the normal vaginal flora balance.

Astodimer sodium (VivaGel®), the active ingredient in Fleurstat BVgel, works by creating a physical barrier that disrupts attachment of the bacteria, which cause BV, to the vaginal lining, thereby allowing the beneficial bacteria to replenish.

Astodimer sodium (VivaGel®) has been shown to be not absorbed into the bloodstream following topical application in the vagina in preclinical and clinical studies. Fleurstat BVgel has been shown to be not carcinogenic (does not cause cancer), not mutagenic (does not cause genetic damage that may lead to cancer), and not teratogenic (does not disrupt development of an embryo or foetus) in laboratory-based studies.

The effect of Fleurstat BVgel on latex and non-latex condoms has been assessed in a number of studies that demonstrated that it did not compromise the integrity or affect the

dimensions of non-lubricated, silicone-lubricated, or aqueous-lubricated condoms.

! Warnings

- For vaginal use only.
- Keep out of reach of children.
- Do not use the product if the applicators are unwrapped or the wrapper is torn.
- Do not use the product if the container/tube is broken or dirty or appears to be tampered with.
- Only use the recommended dose as specified in these instructions.
- Do not use Fleurstat BVgel if you have a history of sensitivity to astodimer sodium, hydroxybenzoates or any other ingredient of the formulation.
- See a doctor if you are pregnant or diabetic. See a doctor if you plan to become pregnant, or are breastfeeding or plan to breastfeed.
- Do not use for more than 7 days unless a doctor has told you to. See a doctor if no better after 7 days. If symptoms recur within two weeks of completing the course, consult a doctor.
- See your healthcare provider if you consider that you may be at risk of a Sexually Transmitted Infection (STI).
- Laboratory-based studies of Fleurstat BVgel have not demonstrated a risk to the foetus, but there are no adequate and well-controlled clinical studies in pregnant or breastfeeding women and the effects on an unborn child have not been fully investigated.
- Fleurstat BVgel should not be used by girls before the onset of puberty.
- Delay administering the normal dose of Fleurstat BVgel when you anticipate sexual activity will occur around bedtime. Administer the normal dose of Fleurstat BVgel after any sexual activity is complete.
- Avoid use of this product with personal / medicinal products containing polyquaterniums.
- Do not share your vaginal applicators with anyone. Dispose of each applicator after dosing.
- Store Fleurstat BVgel below 30°C. Do not refrigerate or freeze.

What does the package contain?

The carton contains:

- one (1) sealed multi-dose aluminium tube containing 45 grams of Fleurstat BVgel, sufficient for seven (7) doses,
- seven (7) disposable vaginal measured dose applicators, and
- one (1) instructions for use leaflet.

Read this 'Instructions for Use' leaflet and retain for future reference.

How much do I use?

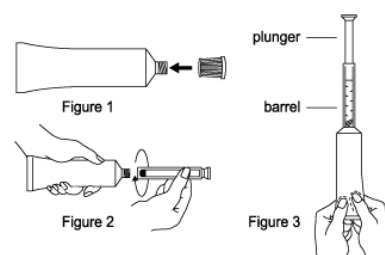
The recommended dose is one applicator full (equivalent to 5g) vaginally once daily, preferably at bedtime, for 7 days. It is

important to complete all 7 doses, even if your symptoms go away.

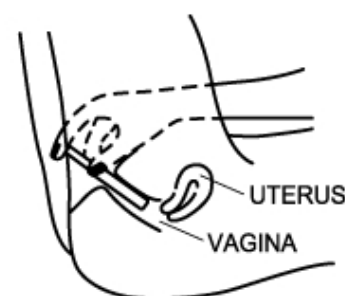
Directions for the multi-dose tube and disposable applicators

A single dose of Fleurstat BVgel (5g) is to be filled into the disposable 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 (Fig. 1).
2. Remove an applicator from the wrapper and screw end of applicator onto tube (Fig. 2).
3. Slowly squeeze the tube from the bottom to fill the applicator with gel; the plunger will move as the applicator fills and will stop moving when the applicator contains the correct amount of gel (Fig. 3).
4. Once filled, unscrew the applicator from the tube and replace the tube cap.
5. The filled applicator is now ready to be applied.

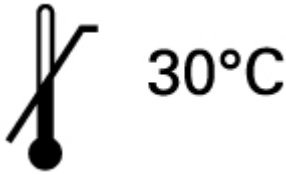


6. The applicator is inserted in the same way you would use a tampon applicator, so you may sit or stand depending on how you feel most comfortable.
7. Hold the applicator barrel between the thumb and middle finger and gently insert the applicator as far as comfortably possible into the vagina



8. Holding the applicator in place, slowly push the plunger until it stops, dispersing the gel into the vagina.
9. Carefully remove the applicator, keeping the plunger depressed.
10. Discard used applicator into a suitable waste container.

Storage



Store Fleurstat BVgel below 30°C.

Do not refrigerate or freeze.

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

Disposal

Dispose of the used tube and applicators responsibly into a waste container.



Dispose responsibly

Frequently Asked Questions

Can I use Fleurstat BVgel during my period?

Yes, you can use Fleurstat BVgel when menstruating.

Will Fleurstat BVgel interfere with sexual intercourse?

No. However, it is recommended to delay administering Fleurstat BVgel if you anticipate sexual activity will occur around bedtime. Administer Fleurstat BVgel after any sexual activity is complete.

Are there any side effects of Fleurstat BVgel?

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 candidiasis (thrush).

Will Fleurstat BVgel interfere with any other products or medicines?

Fleurstat BVgel is not known or expected to interfere with medications because it is not absorbed into the bloodstream following topical vaginal application. Use of other vaginally applied products containing polyquaterniums, which are found in some personal lubricants, should be avoided while using Fleurstat BVgel, as polyquaterniums have been shown to be incompatible with astodimer sodium. No other product interaction studies have been conducted.

When is the best time to use Fleurstat BVgel?

It is recommended to apply Fleurstat BVgel at bedtime.

Can Fleurstat BVgel be used with a condom?

Yes. Fleurstat BVgel has been shown to not compromise the integrity or affect the dimensions of condoms. However, it is recommended to delay administering Fleurstat BVgel if you anticipate sexual activity will occur around bedtime. Administer Fleurstat BVgel after any sexual activity is complete.

When should I see my doctor?

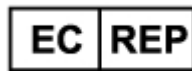
BV is associated with a characteristic 'fishy' vaginal odour and an abnormal greyish-white, thin vaginal discharge. Other common vaginal infections may be associated with intense itching or painful urination, and clumpy or frothy discharge. If you are unsure you have BV, or suspect you have a vaginal infection other than BV, please see your doctor. Also see your doctor if you consider that you may be at risk of an STI, if your symptoms persist or recur, or your condition worsens, as these symptoms may be indicative of another infection including an STI. You should see your doctor before using the product if you are diabetic, pregnant or breastfeeding.

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