

*balance*TM
activ

Vaginal Gel

clinically proven for the rapid relief of embarrassing odour, abnormal discharge and discomfort



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Vaginal infections can be caused by many different types of organism, the most common being:

- An overgrowth of various bacteria, e.g. *Gardnerella vaginalis*, (known as Bacterial Vaginosis (BV)).
- The family of yeasts, *Candida*, which cause Candidiasis, commonly known as a Yeast Infection or Thrush.

It is mistakenly believed that Thrush is the most common type of vaginal infection, but bacterial vaginosis is actually the most frequently occurring condition in women of childbearing age, and is about twice as common as Thrush¹. Experts estimate that at least 1 in 3 women, and perhaps most women, will develop BV at some point in their life.^{2,3,4}

Bacterial Imbalance In The Vagina

In a normal healthy vagina there are a number of different types of harmless bacteria, predominantly *lactobacilli* (lactic acid bacteria). These bacteria produce lactic acid, by their interaction with glycogen present in the vaginal tissues, resulting in a vaginal pH of 3.8 to 4.5. This normal acidity is widely reported to prevent the harmful overgrowth of various pathogens⁵.

A disruption to the normal flora of the vagina, can lead to the opportunistic growth of anaerobic bacteria, such as *Gardnerella vaginalis*, *Prevotella* species, *Mycoplasma hominis*, and *Mobiluncus* species. Overgrowth of these anaerobic organisms can cause an increase in pH of up to 7.0.

This condition is known as bacterial vaginosis or BV.

How Does This Imbalance Occur?

The disruption of the vaginal flora can be caused by a number of external and internal factors including:

- prolonged menstruation, which increases the pH level
- use of IUDs (a 'foreign body' increases protein, making an ideal environment for anaerobic bacteria)
- frequent douching (washing out the normal harmless bacteria along with the unwanted organisms)
- perfumed intimate products
- sex without a condom (semen is alkaline, so it increases the pH level)

The pH of the vagina also alters at different stages in the menstrual cycle and this may be another reason why the bacteria multiply.

BV is not caused by poor hygiene; in fact excessive washing of the vagina may alter the normal balance of bacteria in the vagina making BV more likely to develop. BV is not a sexually transmitted infection and women that aren't sexually active can get BV.



What Are The Symptoms?

The main symptom of BV is usually a thin, white-grey coloured, homogeneous discharge which often has a fishy smell. The discharge tends to be heaviest just after a period and after having sex; the smell may be most noticeable when having sex. Other symptoms may include irritation or soreness in and around the vagina. Itching is reported⁶, although it is disputed⁷, which may be due to misdiagnosis or mixed infections.

Many women with BV do not have any symptoms⁸, and the condition may be only detected as a result of a routine examination.

How Is BV Diagnosed?

In clinical practice, BV is normally diagnosed using the Amsel criteria. At least three of the four criteria must be present for the diagnosis of BV to be confirmed:

1. Thin, greyish white, homogeneous discharge
2. Clue cells on microscopy
3. pH of vaginal fluid > 4.5
4. Release of a fishy odour on adding alkali (10% KOH)

An alternative is to use a Gram stained vaginal smear, and then evaluate by microscopy, with the Hay/Ison criteria or the Nugent criteria.

The Hay/Ison criteria are defined as follows:

- **Grade 1 (Normal):**
Lactobacillus morphotypes predominate
- **Grade 2 (Intermediate):**
Mixed flora with some *Lactobacilli* present, but *Gardnerella* or *Mobiluncus* morphotypes also present
- **Grade 3 (BV):**
Predominantly *Gardnerella* and/or *Mobiluncus* morphotypes. Few or absent *Lactobacilli*

The Nugent score is derived from estimating the relative proportions of bacterial morphotypes to give a score between 0 and 10. A score of <4 is normal, 4-6 is intermediate, and >6 is BV.

The complex nature of these assessments means that clinicians can often misdiagnose BV. For example, in one study, 61% of physicians misdiagnosed BV⁹. Many women self diagnose the condition wrongly as a yeast infection and treat themselves with an anti-fungal; the awareness of BV is relatively low.

What Happens If BV Is Left Untreated?

Without treatment, symptoms may resolve in both pregnant and non-pregnant women. Whilst it is considered unusual for BV to cause complications in otherwise healthy, non-pregnant women, it is thought that both the incidence and importance of BV has been underestimated. It is only through recent research that the presence of BV has been implicated in pelvic inflammatory disease and tubal infertility, and has been shown to increase the risk of acquiring and transmitting HIV¹⁰ and other Sexually Transmitted Infections⁸.

BV is associated with significant complications in pregnant women and in women undergoing gynaecological procedures. In pregnancy, BV is associated with

- pre-term labour
- pre-term birth
- low birth weight
- premature rupture of membranes
- late miscarriage
- chorioamnionitis
- postpartum endometritis

Women with untreated BV have a higher chance of developing an infection of the uterus or endometritis following a termination of pregnancy⁷. After vaginal hysterectomy, BV has been associated with an increased incidence of vaginal cuff cellulites and abscess formation⁷.

Women that think they may have a vaginal infection during pregnancy should consult their doctor.

How Can The Condition Be Treated?

Currently, the conventional prescribed treatment is a course of antibiotics (metronidazole or clindamycin), which are available as a course of oral tablets or as a topical treatment. The cure rate for BV with antibiotic therapy is reported to be 80-90%, but with a recurrence rate of 50-70%.

There are many alternatives which aim to restore the natural vaginal balance, and prevent recurrence, primarily through the process of acidification.

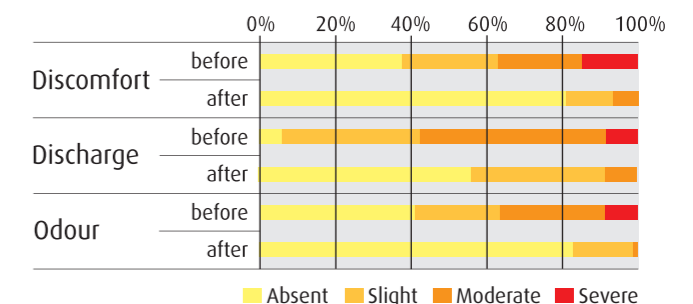
- The application of *lactobacilli* originating from laboratory cultures has been shown to be ineffective: their adherence to the vaginal epithelial cells is poor and the vagina is an unsuitable environment for them to grow.
- Self medication with cold soured milk or yoghurt can have two positive results; partly cooling and partly a temporary pH reduction which can eliminate the odour. Relief using this messy method is temporary. On the contrary, the milk proteins could even favour the growth of the BV bacteria.
- Boric acid and hydrogen peroxide have also been used, but no robust clinical trials have been performed to prove the effectiveness of the methods.
- The application of a buffered gel normalises vaginal pH, immediately neutralising the amines that produce the unpleasant odour. These gels create an environment favourable to natural lactobacilli and conversely an environment less favourable to the BV causing organisms.

A trial was undertaken recently to study the effect of a buffered gel containing lactic acid and glycogen to redress vaginal imbalance (*balance activ*). The overall aim of the trial was to evaluate the effectiveness,

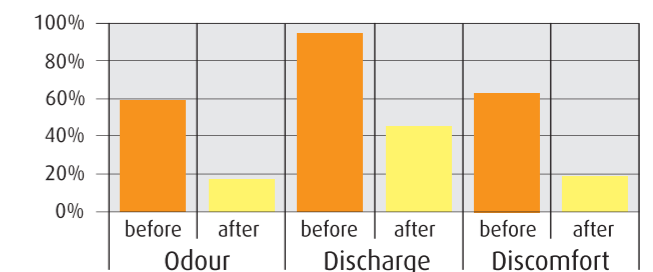
tolerance and acceptability of the lactic acid and glycogen gel in relieving the symptoms resulting from changes to normal vaginal flora. The trial studied 109 cases of vaginosis in women aged 17-65 with an average age of 35.6.

The results of this trial demonstrated that the daily vaginal application of lactic acid and glycogen gel for a period of 7 days proved to be effective in symptom relief. Significant results were reported for all presenting symptoms including: leucorrhoea, pruritis, stinging, bad odour, irritation, pain and vaginal dryness.

Patient assessment of severity of symptoms before and after treatment.



Patient assessment of symptoms before and after treatment.



The vaginal gel was judged by patients to be effective, excellently tolerated and very well received.

The conclusion was that the vaginal gel should be considered as part of a normal symptom relief regime for conditions resulting from vaginal imbalance, such as vaginal odour, discharge and discomfort.

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balance activ vaginal gel

balance activ vaginal gel is a unique product containing both lactic acid, to immediately restore the natural pH of the vagina, and glycogen, to promote the healthy growth of the normal bacteria. With normal pH and nutrients, the protective lactobacilli grow and the natural vaginal balance is restored.

balance activ vaginal gel is easy to use. The gel is contained within a disposable tube; the woman twists off the top, inserts the tube into her vagina, and squeezes out the contents. Then the tube is simply removed and discarded.

Many women experience recurrent symptoms, for example around the time of menstruation, or when taking antibiotics. balance activ vaginal gel can also be used to maintain the natural pH of the vagina and prevent recurrence.

It has been tried and clinically tested to be safe and effective. The product has been used to redress vaginal imbalance in Sweden for more than 10 years.

For Rapid Relief	
For the effective relief of embarrassing odour, abnormal discharge and discomfort	Use 1 tube daily for 7 days
Maintenance and Prevention	
To maintain the natural pH balance and prevent recurrence of symptoms	Use 1-2 tubes a week
To help maintain the pH level during a course of antibiotics	Use 1 tube daily at the end of the course for 4-5 days
If you notice a recurrence of symptoms around the time of your period	Use 1 tube daily at the end of your period for 1-2 days

balance activ vaginal gel restores the natural healthy balance of the vagina.

balance activ vaginal gel is available without prescription.



References

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balance activ vaginal gel

Dual-action *balance activ vaginal gel* restores and preserves the natural pH balance in the vagina, effectively relieving embarrassing odour, abnormal discharge and discomfort. Its unique formulation contains Lactic Acid and Glycogen:

- The Lactic Acid immediately restores the normal pH of the vagina, inhibits the growth of anaerobic bacteria, and neutralises the amines produced by the anaerobes which cause the 'fishy' smelling discharge.
- The Glycogen provides nutrients to promote the growth of lactobacilli, effectively relieving abnormal discharge and discomfort.

It contains no preservatives.

balance activ vaginal gel can also be used to maintain the natural pH balance and prevent recurrence of symptoms.

- **Easy to use** – the gel comes in a disposable applicator tube which is simply inserted into the vagina, squeezed, then removed and discarded.
- **Clinically Proven** – clinical trials have shown that *balance activ vaginal gel* is safe and effective in restoring and maintaining the pH balance of the vagina.
- **Safe to Use** – during pregnancy and during menstruation.

balance activ vaginal gel for the rapid relief of embarrassing odour, abnormal discharge and discomfort.

balance activ is a Class I medical device.

For further information please visit our website www.balanceactiv.com

Manufacturer: Kullgren Pharma, Gnesta, Sweden

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