

**Please read the following package leaflet carefully**, because it contains important information that you need to be aware of when using this medical device. Keep this package leaflet. You may wish to read it again later. If you have any further questions, ask your doctor or pharmacist.

## Vagisan® Lactic Acid

**Pessary for maintaining and restoring natural vaginal pH levels via acidification with lactic acid**

### Ingredients

lactic acid, macrogol 1500, macrogol 6000, sodium lactate

### Indications for use

Vagisan Lactic Acid is used to maintain and restore natural pH levels in the vagina. Using lactic acid to acidify the vaginal environment supports the growth of bacteria typically found in the vagina (lactic acid-producing lactobacilli = lactic acid bacteria), whilst having a negative effect on the growth of disease-causing germs. Vagisan Lactic Acid can therefore be used to prevent vaginal infections in women prone to such conditions and as a supplement to drug therapy in vaginal infections.

### Product information

Vagisan Lactic Acid consists of pessaries containing a mixture of lactic acid and sodium lactate. The pessaries can be used to maintain or regulate natural pH levels in the vagina

- in adult women
- during pregnancy and breast-feeding
- in girls after consultation with a doctor.

Preventive long-term treatment can be safely administered to women who are prone to vaginal infections (see "Using Vagisan").

The pessaries do not contain paraffin, Vaseline or any other fats. They do not affect the tear resistance of latex condoms or diaphragms (caps).

### What you should know about lactic acid and vaginal infections

The cells inside the vaginal wall contain sugar, which is released during normal cell shedding. This sugar is broken down into lactic acid by the lactic acid bacteria in the vagina. If there is enough lactic acid present, the vaginal environment is naturally acidic with a pH of 3.8–4.4. These are adverse conditions for the growth of undesirable bacteria. Therefore, an acidic vaginal environment helps prevent bacterial infections.

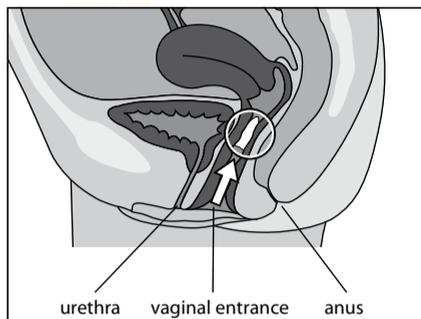
The acidic vaginal environment can be disrupted by various external factors, causing the pH to rise above 4.5. Possible factors include bodily secretions such as menstrual blood or semen, a reduced numbers of lactobacilli due to antibiotics, and fluctuating hormone levels during pregnancy, breast-feeding or as a result of using female sex hormones. Under such conditions, the growth of unwanted germs in the vagina is encouraged. These germs may originate in the area around the vaginal entrance (e.g. anal region) and ascend into the vagina, or they may be transmitted by sexual intercourse, for example. This may result in an overgrowth of the natural lactobacilli flora due to these germs and a vaginal infection.

In women prone to repeated vaginal infections, vaginal use of lactic acid can, in many cases, help support the self-regulation of acidic pH levels.

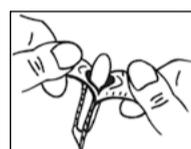
### Using Vagisan

Insert one pessary once daily in the evening before bedtime. You should

insert it as deeply into the vagina as possible. This is best performed lying on your back, with your legs slightly drawn up.



To remove the pessary from the strip, pull apart the two foil layers at the tip of the pessary, as shown in the adjacent diagram.



If the vagina is relatively dry, the pessary can be moistened under running water before insertion to make it even easier to insert.

Because the pessaries dissolve exceptionally well, please wear a panty liner during use, as a watery discharge can occasionally occur.

The duration of administration is generally 5–7 days. For regular maintenance of normal pH levels in the vagina, e.g. in women prone to vaginal infections, Vagisan Lactic Acid can also be safely used two to three times a week over a longer period.

### Instructions for use during pregnancy and breast-feeding

Vagisan Lactic Acid can also be used during pregnancy and breast-feeding.

### Possible side effects

In rare cases, skin reactions (e.g. redness, stinging, itching) may occur. In isolated cases an allergic skin reaction may develop (e.g. severe redness, swelling, burning). If you notice any other unpleasant effects, please talk to your doctor or pharmacist.

### Contraindications

Vagisan Lactic Acid must not be used in cases of known hypersensitivity to any of the ingredients.

### Restrictions on use

Girls should only use Vagisan Lactic Acid after talking to their doctor, as not enough experience has yet been gained to recommend it generally for use in children. Use of Vagisan Lactic Acid is not recommended during menstrual periods. You should skip treatment on these days.

If you have a vaginal infection at the moment (e.g. increased discharge, discharge with an unpleasant odour, itching and stinging at the vaginal entrance), you should consult your doctor before using Vagisan Lactic Acid, so that your symptoms can be diagnosed and appropriately treated. You may need medicine or your partner might also need treatment.

Whilst using Vagisan Lactic Acid, if your vaginal symptoms worsen or do not improve within 8 days, you should stop using the product and consult a doctor.

As Vagisan Lactic Acid contains no spermicides (substances that kill male

sperm), it offers no protection against unwanted pregnancy.

If the pessary strip is damaged or if you notice any change in the appearance of the pessaries, do not use the product and inform the manufacturer.

#### Storage and shelf life

Store Vagisan Lactic Acid out of the reach and sight of children.

Do not store above 30°C.

Do not use Vagisan Lactic Acid after the expiry date which is stated on the strip and flap of the pack after the symbol . The expiry date refers to the last day of that month.

#### Pack sizes

Packs of 7 pessaries for vaginal use

#### Manufacturer

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#### Medical device

CE 0297

#### Date of information

January 2012

DR·WOLFF

Meaning of the symbols on the packaging and strip:				
				 30°C
Batch number	Best before	CE mark	Follow the instructions for use	Do not store above 30°C

#### Vagisan®

for a healthy genital area

- **Vagisan® Lactic Acid**, pessaries (medical device). For a healthy vaginal environment. Acidification with lactic acid *achieves/restores a natural pH in the vagina.*
- **Vagisan® Moisturising Cream** (medical device). For vaginal dryness. Hormone-free cream that supplies moisture AND nourishing lipids (fats). With typical cream-like properties, Vagisan Moisturising Cream alleviates the symptoms of dryness of the vagina and external genital area.

[www.vagisan.com](http://www.vagisan.com)