

Dear Patient

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® Moisturising Cream – Instructions for use

For vaginal dryness

Cream for application in the vagina and to the external genital area

Ingredients

Purified water, benzyl alcohol, cetearyl alcohol, cetyl palmitate, lactic acid, octyl-dodecanol, polysorbate 60, sodium lactate, sorbitan stearate

Vagisan Moisturising Cream contains no fragrances.

Indications for use

For symptoms caused by dryness of the vagina and external genital area (feeling of dryness, stinging, itching and painful intercourse, e.g. during the menopause, due to oestrogen deficiency). Vagisan Moisturising Cream can also be used to facilitate sexual intercourse.

Product information

Vagisan Moisturising Cream is a smooth, white cream developed for use in symptoms of vaginal dryness. Vagisan Moisturising Cream contains no hormones (oestrogens) and can therefore be used alongside hormone replacement therapy or during the menopause with vaginal creams or pessaries that do contain hormones (oestrogen). Thanks to the addition of lactic acid, the cream is set at a pH of 4.5. As a result, Vagisan Moisturising Cream helps maintain a natural pH within the vagina.

Two effects contribute towards the relief of symptoms of vaginal dryness by Vagisan Moisturising Cream:

- The cream has a high water content, thereby moisturising the skin within the vagina and external genital area.
- Nourishing lipids (fats) keep the skin supple.

Regular use of Vagisan Moisturising Cream can help prevent irritation and inflammation within the vagina and external genital area. The cream can also be used for vaginal dryness before sexual intercourse, in principle with latex condoms. In women wishing to conceive, there are no contraindications to using Vagisan Moisturising Cream for vaginal dryness, as sperm motility is not impaired.

What you should know about the symptoms of “vaginal dryness”

The symptoms of vaginal dryness can severely affect the quality of life of those women affected. The sensation of dryness is often accompanied by other discomfort, such as itching, stinging or soreness involving the vagina, vaginal entrance and external genital area. In many cases, these symptoms also make sexual intercourse painful.

Particularly affected are women in the menopause (which, in some cases, starts as early as at 40 years of age) and during the years thereafter. In such cases, vaginal dryness is caused by the decreasing production of sex hormones (including oestrogen). Less vaginal fluid is produced within the vagina; the skin becomes thinner and more fragile. Whilst this process is quite normal, it can bring considerable discomfort.

After womb or ovarian surgery, during pregnancy and breast-feeding or while taking the Pill, hormone deficiency/fluctuations or hormonal imbalance can also lead to symptoms of vaginal dryness.

Some metabolic disorders (e.g. diabetes), medications, radiation treatment for cancer and even stress can also be associated with dryness in the internal and external genital area.

Using Vagisan Moisturising Cream

Vagisan Moisturising Cream is intended for application in the vagina and to the external genital area. Vagisan Moisturising Cream can be applied with or without an applicator.

For symptoms in the vaginal entrance and external genital area, use a clean finger to apply and spread the cream; a ribbon of cream about 0.5cm long is sufficient. To make it easier to insert the applicator, a small amount of cream can also be applied to the area around the vaginal entrance.

Vagisan Moisturising Cream can be inserted into the vagina using the applicator provided.

To do this, fill the applicator halfway (about 2.5g cream, see also “Directions for use”). The cream should be applied daily, preferably in the evening before bedtime (if necessary, wear a panty liner). Once symptoms have improved, you can reduce how often you use the cream, depending on your needs.

The cream can also be used before sexual intercourse or during menstrual periods.

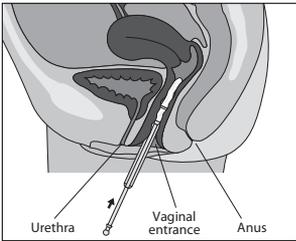
If Vagisan Moisturising Cream is well tolerated, it can also be used over prolonged periods, or during pregnancy (without the applicator; see Instructions for use during pregnancy) and breast-feeding.

Directions for use

- Loosen the plunger, so that it can be moved inside the applicator barrel
- With the tube opening facing upwards, attach applicator onto tube opening

- Fill the applicator barrel halfway with cream (about 2.5g cream), by gently and evenly squeezing the tube
- Remove the applicator from the tube
- You can insert the applicator into the vagina whilst lying down (on your back) or standing up (like when inserting a tampon). Carefully insert the applicator as deeply as possible into the vagina; push the plunger to empty the applicator and insert the cream into the vagina (see diagram).
- After use, clean the applicator as follows: firmly press the spherical end of the plunger onto a firm surface. This will separate the plunger from the applicator barrel. Then clean the plunger and barrel separately in warm water.

Inserting the applicator into the vagina



Instructions for use during pregnancy

For safety reasons, the applicator should not be used to insert the cream during pregnancy. Instead, a ribbon of cream about 2cm long can be inserted into the vagina using a clean finger.

Possible side effects

Uncommon: mild local irritation (itching, stinging) may temporarily occur, as well as a slight discharge in some cases. Very rare: hypersensitivity reactions (e.g. redness, stinging) may occur. If such symptoms persist and do not improve, you should stop using Vagisan Moisturising Cream and consult a doctor. If you notice any other unpleasant effects, please talk to your doctor or pharmacist.

Restrictions on use

Vagisan Moisturising Cream must not be used in cases of known hypersensitivity or allergy to any of the ingredients. The cream must not be used immediately after childbirth. Simi-

larly, do not use Vagisan Moisturising Cream if you have a vaginal infection (e.g. thrush); in this event, you should talk to your doctor. If the tube or applicator is damaged, or if there are any changes in the appearance of the cream, do not use the product and inform the manufacturers.

Storage and shelf life

Store Vagisan Moisturising Cream out of the reach and sight of children.

Keep the tube tightly closed.

Do not store above 25°C.

Do not use Vagisan Moisturising Cream after the expiry date which is printed on the flap of the packaging and/or tube crimp.

After opening, the cream can be kept for a period of 6 months.

Pack sizes

Tube packed in an outer carton, containing 50g cream for application in the vagina and to the external genital area.

The pack also contains an applicator (CE-certified) for vaginal insertion of the cream.

Manufacturer

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Medical device

CE 0297

Date of information

June 2010

DR·WOLFF

Meaning of the symbols on the outer pack and tube:				
Batch number	Best before	CE marking	Follow the instructions for use	Do not store above 25°C

Vagisan®

for a healthy genital area

- **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.
- **Vagisan® Lactic Acid**, Vaginal Pessaries (medical device). For a healthy vaginal environment. Acidification with lactic acid achieves/restores a natural pH in the vagina.

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