

**Dear User,**

**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® MoistCream

### – Instructions for use –

#### For vaginal dryness

#### Cream for application in the vagina and to the skin of the external genital area

#### Ingredients

Aqua, Benzyl Alcohol, Cetearyl Alcohol, Cetyl Palmitate, Lactic Acid, Octyldodecanol, Polysorbate 60, Sodium Lactate, Sorbitan Stearate.

Vagisan MoistCream contains no fragrances.

#### Indications for use

For symptoms caused by dryness of the vagina and external genital area (dryness, stinging, itching, minor lesions and pain during intercourse, e.g. during the menopause due to an oestrogen deficiency). Vagisan MoistCream can also be used to facilitate sexual intercourse.

#### Product information

Vagisan MoistCream is a smooth, white cream developed for use in symptoms of vaginal dryness. Vagisan MoistCream contains no hormones (oestrogens) and can therefore be used alongside hormone replacement therapy or alternating 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 MoistCream helps maintain a natural pH within the vagina. Two effects contribute towards the relief of symptoms of vaginal dryness by Vagisan MoistCream:

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

Regular use of Vagisan MoistCream may 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 women wishing to conceive, there are no contraindications to using Vagisan MoistCream 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, minor lesions and soreness involving the vagina, vaginal opening and external genital area. In many cases, these symptoms also make sexual intercourse painful.

Commonly affected are women in 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 MoistCream

Vagisan MoistCream is intended for application in the vagina and to the external genital area.

For treatment of vaginal symptoms, Vagisan MoistCream is inserted into the vagina. The cream can be applied with the applicator provided, or without an applicator. If you use the applicator, fill it halfway (about 2.5 g cream, see also “Directions for use”). To make it easier to insert the applicator, a small amount of cream can also be applied to the area around the vaginal entrance. If you prefer not to use the applicator, a ribbon of cream about 2 cm long can be inserted into the vagina using a clean finger. 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.

For symptoms in the vaginal opening and external genital area, use a clean finger to apply and spread the cream up to several times a day as needed; a ribbon of cream about 0.5 cm long is sufficient.

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

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

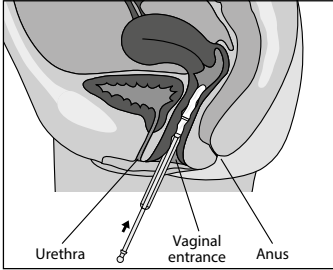
#### Directions for use

- 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 2.5 g 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 2 cm long can be inserted into the vagina using a clean finger.

### Notes for use before sexual intercourse

The cream can be used before sexual intercourse to help to alleviate symptoms of vaginal dryness. Based on the very latest findings, the tear strength of condoms and caps/diaphragms (made of latex or polyurethane or polyisoprene) can be compromised with simultaneous use of Vagisan MoistCream; as a precautionary measure the cream should therefore not be used with condoms or caps/diaphragms.

### Possible side effects

Mild local irritation (itching, stinging) may temporarily occur. Rare: strong skin irritation and hypersensitivity reactions (e.g. redness, itching, stinging) may occur that may persist a while longer. If such symptoms persist and do not improve, you should stop using Vagisan MoistCream and consult a doctor. If you notice any other unpleasant effects, please talk to your doctor or pharmacist.

### Restrictions on use

A doctor should be asked for advice in cases of more severe symptoms caused by vaginal dryness (e.g. interfering with normal activities) and in case Vagisan MoistCream should not sufficiently alleviate symptoms of vulvovaginal dryness.

Vagisan MoistCream does not contain any spermicides (i.e. substances that kill sperm) and therefore does not protect against unwanted pregnancy.

Vagisan MoistCream 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. Similarly, do not use Vagisan MoistCream 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 manufacturer.

### Storage and shelf life

Keep Vagisan MoistCream out of the sight and reach of children.

Keep the tube tightly closed and do not store above 25 °C.

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

After opening, the cream has a shelf life of 6 months.

### Pack sizes

Tube packed in an outer carton, containing 10g (sample size), 25g and 50g cream.

The 10g and 50g pack contain an applicator (CE-certified) for vaginal insertion of the cream.

Not all pack sizes may be marketed.

### Manufacturer

Dr. August Wolff GmbH & Co. KG Arzneimittel  
Sudbrackstrasse 56

33611 Bielefeld, GERMANY

Tel.: +49 521 8808-05

Fax: +49 521 8808-334

E-mail: [info@wolff-arzneimittel.de](mailto:info@wolff-arzneimittel.de)

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

### Medical device

CE 0297

### Date of revision of the text

May 2017

DR·WOLFF

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