

Instructions for use

Remifemin® Moisturising Cream

Nourishing vaginal cream – to treat vaginal dryness

Please read the following instructions for use carefully.



They contain important information that you should be aware of when using this medical device. Please keep these instructions for use; you may wish to read them again later. If you have any questions, ask your doctor or pharmacist.

Ingredients

Aqua, octyldodecanol, cetearyl alcohol, polysorbate 60, hamamelis virginiana water, cetyl palmitate, sorbitan stearate, sodium lactate, benzyl alcohol, lactic acid. Remifemin® Moisturising Cream does not contain any colorants or scents.

Indications for use

For complaints due to dryness of the vagina or the exterior genital area (sensation of dryness, burning, pain during sexual intercourse or itching) which for example can occur during menopause. For ease of sexual intercourse. Remifemin® Moisturising Cream physically supports the healing process of minor injuries, which are sometimes associated with the vaginal mucosa thinning and becoming more vulnerable.

Product information

Remifemin® Moisturising Cream is a pleasantly smooth cream developed to treat symptoms of vaginal dryness. It is free from hormones (estrogens) and can, therefore, also be used in combination with hormone therapy or alternately with vaginal creams or vaginal suppositories containing hormones (estrogens). Remifemin® Moisturising Cream has a positive effect on the vaginal flora: by adding lactic acid, the cream has a pH of 4.2 – 4.5 and thus helps maintain the natural pH level in the vagina. Two effects of Remifemin® Moisturising Cream that contribute to the relief of symptoms associated with vaginal dryness are:

- the high water content of the cream supplies the skin in the vagina and the surrounding genital area with moisture
- the soothing lipids (fats) keep the skin supple.

Remifemin® Moisturising Cream rapidly calms and restores irritated skin.

Regular application of Remifemin® Moisturising Cream can help prevent vaginal and exterior genital area irritation and promotes optimal vaginal health. The cream can be used to treat vaginal dryness before sexual intercourse.

Hamamelis water

Remifemin® Moisturising Cream contains hamamelis water, a steam distillate of freshly cut branches and leaves of the Virginian witch hazel (*Hamamelis virginiana* L.). The plant has been used in Native American medicine for centuries. Nowadays, Hamamelis preparations are used in cosmetics, medicinal products and medical devices.

What you should know about "vaginal dryness"

The symptoms associated with vaginal dryness can severely impair the quality of life of those women affected. The feeling of dryness is often accompanied by further discomfort such as itching, burning, and pain in the vagina, at the vaginal entrance and in the exterior genital

area. In many cases, these symptoms can also make sexual intercourse painful. Women are particularly affected during menopause (some starting at the age of 40) and during the years thereafter, when the symptoms are caused by the decreasing production of sexual hormones (including estrogens). Less vaginal fluid is produced in the vagina, and the skin becomes thinner and more vulnerable. Even though this is a very normal process, it can result in considerable discomfort. Symptoms of vaginal dryness may also result from hormone deficiency and hormonal fluctuations or imbalances caused by uterine or ovarian surgery, pregnancy, breast-feeding, or taking the "pill". Moreover, some metabolic disorders (e.g. diabetes), certain medications, radiation for tumours, and even stress can contribute to developing symptoms of vaginal dryness.

Application of Remifemin® Moisturising Cream

Remifemin® Moisturising Cream is intended for application in the vagina and to the skin of the exterior genital area. Remifemin® Moisturising Cream can be applied with or without the enclosed applicator. Attention should be paid to good hygiene in the genital area and clean hands. For symptoms at the vaginal entrance and in the exterior genital area, use a clean finger to apply and spread the cream; a strip of cream about 0.5 cm 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 and around the applicator opening.

Remifemin® Moisturising Cream can be inserted into the vagina using the applicator provided. For this purpose, fill the applicator halfway (about 2.5 g cream), see also "Directions for use". The cream should be applied once a day – preferably in the evening before bedtime (if necessary, wear a panty liner). After the symptoms have improved, the cream can be applied less frequently.



A 2-day break should be taken after 30 days of continuous use.

The cream can also be used immediately before sexual intercourse. It is not necessary to discontinue application during menstruation. During pregnancy Remifemin® Moisturising Cream can be used without the applicator (see "Instructions for use during pregnancy".)

Directions for use with applicator

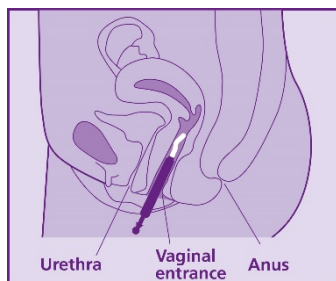
- Loosen the plunger, so that it can be moved inside the applicator barrel.
- With the tube opening facing upwards, attach the applicator to the tube opening.
- Fill the applicator barrel halfway with cream (about 2.5 g cream), by gently and evenly squeezing the tube.
- Remove the applicator from the tube.
- You can insert the applicator into the vagina while lying down (on your back) or standing up (like when inserting a tampon). Carefully insert the applicator

This is the English translation of the German version of the instructions for use, adapted for the address details of the distributors.

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as deeply as possible into the vagina; push the plunger to empty the applicator (see illustration).
 - After use, clean the applicator as follows: Firmly press the ball-shaped end of the plunger onto a hard surface. This will separate the plunger from the applicator barrel. Then clean the plunger and applicator barrel separately in warm water.

Inserting the applicator into the vagina



Instructions for use during pregnancy

Experience on the use of Remifemin® Moisturising Cream during pregnancy and breast-feeding is not available. If you wish to use Remifemin® Moisturising Cream during pregnancy, the applicator should, for safety reasons, not be used to insert the cream into the vagina. Instead, a strip of cream about 2 cm long can be inserted into the vagina using a clean finger.

Instructions for use in combination with condoms

The cream can be used to treat vaginal dryness before sexual intercourse. When using Remifemin® Moisturising Cream simultaneously with condoms, please make sure that the condoms are latex-free, i.e. made of polyurethane (PU), in order not to compromise the integrity of the condoms.

Possible side effects


Temporary, slight local reactions such as redness, itching or a slight burning sensation may occur after application. Skin irritation or hypersensitivity reactions are rarely intense and rarely last long. If such symptoms do not improve, you should stop using Remifemin® Moisturising Cream and consult a doctor. If you notice any other unpleasant effects, please talk to your doctor or pharmacist.


Restrictions of use

If the symptoms caused by dryness are more pronounced, you should seek medical advice first. Remifemin® Moisturising Cream must not be used if you are hypersensitive or allergic to any of the ingredients. Do not use the cream immediately after childbirth. Similarly, do not use Remifemin® Moisturising Cream if

you have a vaginal infection (e.g. vaginal yeast infection). In this case, 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 please inform the manufacturer.

Storage and shelf life

 Keep Remifemin® Moisturising Cream out of the reach and sight of children. Keep the tube closed. Store above +2°C. Avoid temperatures above +30°C. The expiry date is printed on the flap of the packaging and/or the tube end. Do not use Remifemin® Moisturising Cream after that date.

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

Pack sizes

Original size with 50 g cream (with applicator). The applicator is used to insert the cream into the vagina.

Manufacturer

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Medical device

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Meaning of the symbols on the outer pack and tube:							
							
batch number	use-by date	CE-mark	consult instructions for use	usable for 6 months after opening	Temperature limit: Storage not below +2°C and not above +30°C	Manufacturer	Caution