

Dear patient, please read the following instructions for use carefully.

They contain important information which 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.

Remifemin® Moisturising Cream

Instructions for use

Soothing vaginal cream – in case of vaginal dryness

Ingredients

Aqua, octyldodecanol, cetearyl alcohol, polysorbate 60, hamamelis virginiana water, cetyl palmitate, sorbitan stearate, sodium lactate, benzyl alcohol, lactic acid, Remifemin® Moisturising Cream contains neither colorants nor scents.

Indications for use

For complaints due to vaginal dryness and in the exterior genital area (sensation of dryness, stinging, pain during sexual intercourse or itching) which for example 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 becoming thinner and more vulnerable.

Product information

Remifemin® Moisturising Cream is a pleasantly smooth cream developed for use in symptoms of vaginal dryness. It is free of hormones (estrogens) and can, therefore, also be used in combination with hormone therapy or in turns with hormone- (estrogen-) containing vaginal creams or vaginal suppositories. Remifemin® Moisturising Cream has positive effects on the vaginal flora: by the addition of lactic acid the cream is set at a pH-value of 4.2 – 4.5 and thus supports maintaining a natural pH-value within the vagina.

Two effects contribute to the relief of symptoms of vaginal dryness by Remifemin® Moisturising Cream:

- Due to the high water content of the cream the skin within the vagina and the exterior genital area is moisturized.
- Soothing lipids (fats) keep the skin supple.

Remifemin® Moisturising Cream rapidly calms and rebalances the irritated skin.

Regular application of Remifemin® Moisturising Cream can help to prevent irritations within the vagina and in the exterior genital area and enhances an optimal vaginal health. The cream can be used in case of vaginal dryness before sexual intercourse.

Hamamelis water

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

What you should know about the symptoms of "vaginal dryness"

The symptoms of vaginal dryness can severely impair the quality of life of those women affected. The sensation of dryness is often accompanied by further discomfort

such as itching, stinging and soreness involving the vaginal area, the vaginal entrance and the exterior genital area. In many cases, these symptoms also make sexual intercourse painful. Particularly affected are climacteric women (in some cases already starting from the age of 40) and during the years thereafter. In such cases the complaints are caused by the decreasing production of sexual hormones (including estrogens). Less vaginal fluid is produced within the vagina, the skin becomes thinner and more vulnerable. Whilst this is a quite normal process, it can result in considerable discomfort. Also after uterine or ovarian surgery, during pregnancy and breast-feeding or while taking the "pill", hormone deficiency, hormonal fluctuations or imbalances can result in symptoms of vaginal dryness. Moreover, some metabolic disorders (e.g. diabetes), certain medications, radiation therapy in case of tumour diseases 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 an applicator. In this connection, attention should be paid to good hygiene in the genital area and clean hands. For symptoms in the vaginal entrance and in the exterior genital area use a clean finger to apply and spread the cream; a ribbon of the 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.

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 daily – preferably in the evening before bedtime (if necessary, wear a panty liner). After symptoms have improved, the frequency of applying the cream can be reduced. Please interrupt the application for at least two days after 30 days of continued use at the latest.

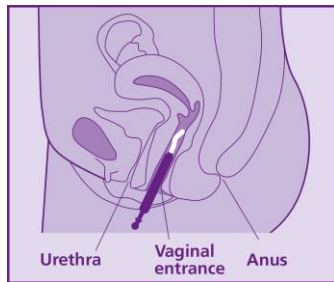
The cream can also be used immediately before sexual intercourse. It is not necessary to discontinue the application during menstruation. During pregnancy Remifemin® Moisturising Cream can be used without applicator (see instructions for use during pregnancy).

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 applicator onto 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 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 (see illustration)
- 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 applicator barrel separately in warm water.

Inserting the applicator into the vagina



Instructions for use during pregnancy

Experiences on the use of Remifemin® Moisturising Cream during pregnancy and breast-feeding are 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 ribbon 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 may be used before sexual intercourse in case of vaginal dryness. When using Remifemin® Moisturising Cream simultaneously with condoms, please take care that the condoms are free of latex, e.g. made of polyurethane (PU), in order not to impair the intactness of the condoms.

Possible side effects

After application mild local reactions such as itching or mild stinging are temporarily possible. Severe irritations of the skin or hypersensitivity reactions (e.g. redness, itching, stinging) may occur which might be of longer duration. No data are available regarding the frequency. If such complaints 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 complaints caused by dryness are more pronounced, you should first seek medical advice. Remifemin® 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. Similarly, do not use Remifemin® Moisturising Cream if you have a vaginal infection (e.g. vaginal yeast infection); 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 Remifemin® Moisturising Cream out of the reach and sight of children. Keep the tube closed and store it preferably at a temperature of above +2°C. Avoid temperatures above +30°C. The expiry date is printed on the flap of the packaging and/or tube crimp. 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 (CE-certified) serves for insertion of the cream into the vagina.

Manufacturer

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Medical device

CE 0481

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Meaning of symbols on the outer pack and tube:					
Batch description	Use by	CE-Mark	Refer to instructions for use	After opening 6 month	Storage not below +2°C and not above +30°C