



Premeno[®] duo

Do you suffer from vaginal dryness or fungal infections?

Premeno duo, the new way to achieve vaginal hydration.

*That's good –
all the
information
and tips in
a handy
booklet.*

**This information is for
women who suffer from:**

- Vaginal dryness, including occurrences during and after the menopause.
- Recurring Candida infections (see page 11).



Medical product CE 0124



Premeno[®] duo

- contains no hormones
- adheres perfectly to the vaginal wall
- restores moisture levels in the vagina
- absorbs fluid up to 1000 times its own weight
- has excellent lubricating (sliding) properties
- helps wounds to heal
- has a long-lasting action and needs to be used only once every 3 days
- has the appropriate pH (degree of acidity)
- inhibits the growth of Candida
- is a handy ovule, so no messing around with gels and applicators
- is widely available from pharmacists (see order form at the back of this leaflet) or from the internet pharmacy

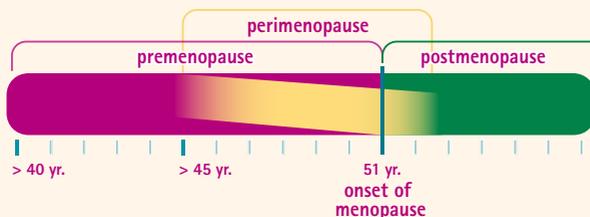
Premeno[®] duo vaginal ovules are also available for younger women suffering from vaginal dryness who are not undergoing the menopause

Menopause

The menopause is a natural process that every woman undergoes at some time after the age of 40. From a woman's first period, her body is set up to have children. The sex hormone oestrogen plays an important role here. However, during menopause, the production of this hormone by the ovaries greatly decreases. The ovaries slowly decrease in size. During menopause, a new hormone balance is established, which for many women may be associated with a variety of symptoms.

What actually is the menopause?

The menopause can be divided into a number of stages relating to the pattern of menstruation. These are based on averages and the age limits vary from one woman to another.

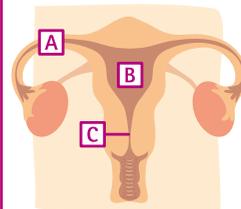


Premenopause

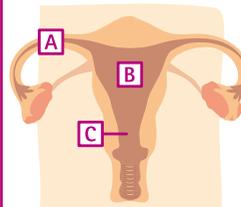
The first stage comprises the premenopause, which most women notice as a change in the pattern of menstruation. Periods remain regular but are in general shorter and often heavier. As the premenopause progresses, the menstrual cycle becomes more irregular and there are longer intervals between menstrual bleeding.

A new stage was recently added called the perimenopause, which covers the late part of the premenopause (> 45 years) through to 1 year after the menopause. During this stage, most women experience typical menopausal symptoms in addition to changes in menstruation.

Childbearing age



Postmenopause



A Fallopian tube

B Uterus

C Cervix

The menopause

The menopause is the time at which the last period takes place. This moment can only be determined after the event, when no menstruation has occurred for 1 year. In the Netherlands, the average age of menopause is 51 years. Ninety percent of 56-year-olds have already undergone the menopause and their fertile years are over.

The postmenopause

This is the stage at which no further menstruation occurs. For the first 5 years, the ovaries are still slightly active. Typical menopausal symptoms such as hot flushes, perspiration, etc. subside during the late postmenopause, but vaginal symptoms often persist. The late postmenopause actually refers to the rest of the woman's life.

Menopausal symptoms

Up until recently it was accepted that about two thirds of menopausal women experience these symptoms and that the rest undergo the menopause almost without symptoms. However, in Finland it was shown that almost 95% of women aged 52-56 years reported mild, moderate or severe forms of one of the following menopausal symptoms.

Typical menopausal symptoms

- severe perspiration (including at night)
- hot flushes
- vaginal dryness
- dyspareunia (painful intercourse)
- reduced libido
- recurring urinary infections*
- involuntary urination*

Non-typical menopausal symptoms

- depression*
- sleep disorders*
- irritability
- dizziness*
- palpitations*

** These are not symptoms you can treat yourself, so contact your doctor. Of the above menopausal symptoms, **Premeno*** duo is effective only in vaginal dryness and can prevent painful intercourse by helping to heal wounds and cracking in the vagina.*

Vaginal dryness

Vaginal dryness before and after the menopause results from a change in the hormone balance. This is a normal and natural process. In particular, the production of the hormone oestrogen rapidly decreases. This results in vaginal tissue and the epithelial layer becoming thinner, drier and less elastic. This is associated with symptoms such as itching, burning, dry vagina, pain, painful intercourse and redness of the labia. The tissue also becomes more susceptible to vaginal infections.

It is often said that the vagina is made up of mucous membranes, but this is a misconception. The vaginal tissue is made up of epithelium, the same skin structure that is present over the rest of the body.

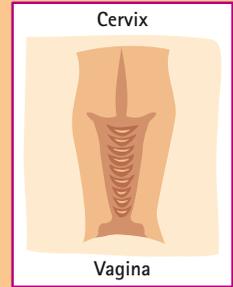
Hyaluronic acid

Decreasing oestrogen levels also cause the levels of another important substance, hyaluronic acid, to decrease in the vaginal tissue during the menopause.

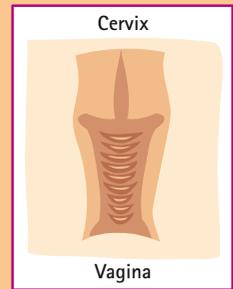
What is hyaluronic acid?

Hyaluronic acid occurs naturally in vaginal tissue. It is what is known as a polysaccharide (a complex sugar) and is found between tissue cells. In this intracellular space, hyaluronic acid ensures that water and nutrients flow into the tissue. Its ability to take up water a thousand times its own volume means hyaluronic acid plays an important role in tissue hydration. Furthermore, it has an important role in maintaining the strength and elasticity of the vaginal connective tissue. Hyaluronic acid promotes the formation of blood vessels and plays an important role in wound healing.

Childbearing age

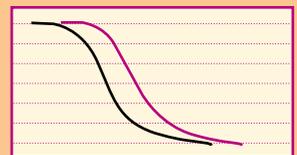


Postmenopause



The vaginal tissue becomes thinner

Decrease in oestrogen and hyaluronic acid levels during the menopause



Menopause

- Oestrogen
- Hyaluronic acid

Premeno[®] duo vaginal ovules

Before, during and after the menopause, many women find that the walls of their vagina become drier. This results in an uncomfortable or burning sensation, itching, irritation, painful intercourse and the formation of wounds or cracking. Many women therefore 'feel less like having sex'. There is now a solution to this discomfort because Premeno[®] duo vaginal ovules contain hyaluronic acid and give back what nature has taken away.

What is Premeno[®] duo used for?

- Premeno[®] duo is a supportive treatment for the correction of vaginal dryness, including during and after the menopause.
- Premeno[®] duo supports the recovery of tissues and promotes wound healing, even after childbirth or chemotherapy.

What do Premeno[®] duo vaginal ovules contain?

Each vaginal ovule contains 5 mg hyaluronic acid. The other ingredients are: lactic acid, sodium lactate, fats, cetareth, beeswax, sorbitan, monostearate and macrogols. Premeno[®] duo contains no synthetic preservatives and has no odour or taste.



Premeno[®] duo gives
back what nature
has taken away.

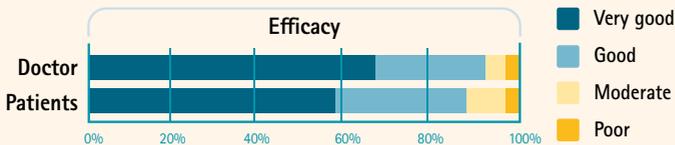
For the dosage, see
the package leaflet
information further
on in this booklet.

For whom are Premeno®duo vaginal ovules suitable?

- For women with vaginal dryness during and after menopause.
- For women who believe hormonal treatment is undesirable.
- For women undergoing the menopause who want to supplement their hormone replacement therapy.
- For women who want long-term vaginal hydration.
- For women who have vaginal dryness due to the use of medicines, e.g. antidepressants.
- Also for younger women who have these symptoms, caused by childbirth or stress.
- For younger women who regularly suffer recurring vaginal fungal infections.

Clinical study

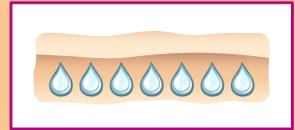
A study carried out among 150 postmenopausal women at 4 menopause clinics and gynaecology practices showed only 9% of the women still had vaginal dryness after 4 weeks of treatment.



Premeno®duo absorbs water up to 1000 times its own weight.



Premeno®duo has a biological effect so that it adheres perfectly to the vaginal epithelium.



Premeno®duo deeply penetrates and moisturizes tissue, supports connective tissue and makes it more elastic, improves perfusion and helps to heal wounds and fissures caused by vaginal dryness.

In another study conducted in women who developed vaginal dryness as a result of breast cancer treatment, ovules containing hyaluronic acid significantly improved the following symptoms:

| Change in symptoms during the study | | | |
|---|----------------|---------------------|----------------|
| Reduction in symptoms at the end of the study (%) | | | |
| Symptoms | A reduction of | Symptoms | A reduction of |
| Dryness | 71,0 % | Burning | 66,1 % |
| Pain | 72,7 % | Itching | 85,0 % |
| Burning sensation | 30,3 % | Fissures (cracking) | 78,3 % |
| Dyspareunia (painful intercourse) | 50,5 % | Redness | 78,5 % |
| Tight sensation | 79,5 % | Inflammation | 86,7 % |

n = 100

Where can I buy **Premeno**[®] duo vaginal ovules?

Premeno[®] duo vaginal ovules are a non-prescription treatment, available only at the pharmacist. The best thing to do is to fill in the order form on the back page. You can also order **Premeno**[®] duo via the internet pharmacy – see the link on the website. Your order will then be dealt with here. Please note that this will incur shipping costs.

What does a pack look like and what does **Premeno**[®] duo cost?

The pack is shown opposite. **Premeno**[®] duo vaginal ovules are packed in boxes of 10 vaginal vaginal suppositories. Each pack contains 2 strips of 5 ovules. The retail price at Europe of one 10-ovules pack is about €12.95 including local VAT. This is also the monthly cost during maintenance treatment.



A few facts about vaginal dryness:

- Large studies have shown that 55% of menopausal women experience vaginal dryness.
- It was previously thought that a reduction in vaginal moisture did not occur until many years after the menopause. Current opinion, however, is that it can also be a problem in the early menopause.
- Insufficient vaginal hydration occurs in 25% of perimenopausal women and in more than 50% of postmenopausal women in their fifties. It is found to be as problematic as the more recognizable menopausal symptoms such as hot flushes and perspiration.
- Unlike other menopausal symptoms, vaginal dryness worsens rather than subsides with age.
- Insufficient vaginal hydration often leads to itching, irritation, a burning sensation, painful urination and painful intercourse.
- Vaginal dryness is directly associated with problems during intercourse due to a lack of lubrication (sliding ability) but after the menopause it is also a common complaint unrelated to intercourse.



*You can order
Premeno[®]duo easily
via the website.*

Tips

- Regular sexual activity is recommended to maintain vaginal health and blood flow (Journal of Obstetrics and Gynaecology Canada 2004;26(5):503–8).
- If, before using **Premeno**[®]duo vaginal ovules, you have a malodorous or white crumbly discharge, then contact your doctor/gynaecologist first.
- Try to wear cotton underwear as much as possible.
- Do not use vaginal douches or perfumed soap; wash only externally with water.
- Take time to get used to all the changes in your body.
- Get enough sleep and don't take on too many activities.
- Eat healthily and try to watch your weight.
- Alcohol, coffee and tea can make hot flushes worse.
- Wear several thin layers of clothing if you suffer hot flushes. If you get too warm then remove a layer.

Premeno[®] duo and vaginal infections

Candida (fungal) infections in younger and older women

Vaginal Candida infections are often associated with unpleasant inflammatory symptoms of the vaginal tissue. Redness on the inside of the labia, accumulation of fluid in the tissue, an itching and burning feeling, cracking and pain, including during intercourse, are common. The vaginal discharge is odourless and appears white and crumbly.

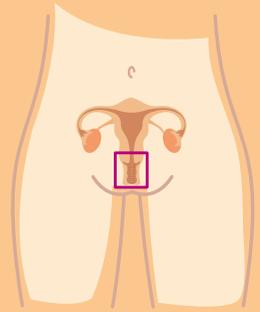
If you have these symptoms, please consult your general practitioner, who will first diagnose you and will prescribe you a course of antifungal product. Many women often develop another Candida infection shortly afterwards.

In particular after using a short-term course of a current antifungal product such as fluconazole, the vaginal tissue often still has yet to recover. Fissures and wounds form, which often allow Candida to gain a foothold in the vaginal tissue again, resulting in a recurring pattern of the disease.

By using **Premeno[®] duo** directly after a course of antifungal product, the tissue, damaged as a result of the vaginal infection, heals more rapidly because of the product's wound-healing properties, making the vaginal tissue less susceptible to another infection.

It has also been shown that hyaluronic acid, the active ingredient in **Premeno[®] duo** vaginal ovules, has an inhibitory effect on the growth of Candida and its attachment to tissue cells.

Premeno[®] duo can therefore also be used to prevent Candida infections.





Premeno[®] duo for younger and older women.

Dose in Candida infections:

The following applies only to use during a course of antifungal product: Insert 1 ovule once daily before bed for 20 days. A maintenance dose of 1 ovule every 3 days may be used. At the beginning of treatment, a mild, transient burning sensation may be felt in rare cases.

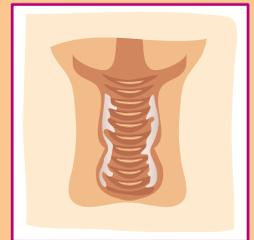
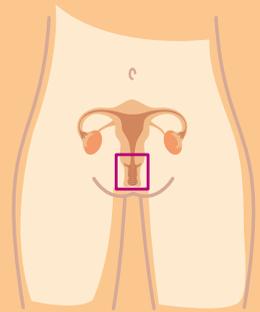
If you had a "one day" anti-mycotic treatment you have to wait for 5 days before starting **Premeno[®] duo**.

Bacterial vaginosis around menopause

During the menopause, oestrogen levels fall. Oestrogen ultimately contributes to the production of lactic acid in vaginal tissue. The main purpose of this is that lactic acid ensures that the vagina is an acidic environment (pH 3.8-4.5), forming a natural barrier to vaginal infections.

Vaginal dryness and an increased risk of vaginal infection are known to be caused by the same hormonal changes.

Bacterial vaginosis is a vaginal infection that may occur during the menopause due to changing hormone levels, leading to an imbalance in the vaginal flora.



Bacterial vaginosis is characterized by the following:

- reduced acidity in the vagina (pH higher than 4.5).
- absence of Lactobacillus that produces lactic acid.
- a generally thin, greyish white discharge with an unpleasant 'fishy' odour, noticeable especially during intercourse.
- vaginal tissue does not generally become red or inflamed. Sometimes irritation of the labia and vagina occurs.
- intercourse is not painful.

The addition of lactic acid to **Premeno**[®]duo pessaries ensures an optimum degree of acidity in the vagina.

Premeno[®]duo restores the 'healthy' pH level in the vagina by replacing the lactic acid naturally present before the menopause.

The dual action of **Premeno**[®]duo (through the use of hyaluronic acid and lactic acid in the ovule) is therefore an ideal, additional combination treatment for preventing bacterial vaginosis in menopausal women.

Dosage in bacterial vaginosis during menopause:

Loading dose: Insert 1 ovule in the evening before bed for 10 consecutive days.

Maintenance treatment: for a lasting effect, insert 1 ovule every 3 days after finishing the loading dose, for as long as you consider appropriate.

Candida infections and bacterial vaginosis are not sexually transmitted diseases.

If you suspect that your vaginal discharge symptoms are the result of a sexually transmitted disease, contact your health centre or STD clinic.

Product information

Composition

Sodium hyaluronate, lactic acid, sodium lactate. Other ingredients: fats, cetareth, beeswax, sorbitan monostearate, macrogols.

General information

The vaginal epithelium (that forms the wall of the vagina) possesses a mechanism for the precise regulation of moisture levels, elasticity and acidity of the vagina. In some situations, this regulatory mechanism may change or be disrupted, as follows:

- during or after the menopause,
- after childbirth during breastfeeding
- during the use of hormone products in mental disorders (stress)
- after cancer treatment (chemotherapy).

This may result in the vagina becoming dry or in insufficient vaginal secretions being produced. This often causes symptoms such as itching, chafing, a burning sensation during intercourse and an increased risk of inflammation. Mechanical irritation, such as intercourse, may cause the epithelium to become damaged and small wounds to appear. If the physiological production of lactic acid also decreases, there is an increased risk of vaginal infection and thus of vaginal inflammation (bacterial vaginosis), with an unpleasant malodorous discharge, increases.

Premeno duo has a dual action, i.e. it simultaneously treats two vaginal disorders:

- Hyaluronic acid

In the first place, this substance ensures that the skin and mucous membrane remain moist and elastic. It also plays an important role in the healing process and tissue recovery. Recent research has showed that this substance also inhibits the growth of *Candida albicans*, the most common causative agent of vaginal mycosis (fungal infection of the vagina). Oestrogen deficiency during and after the menopause may lead to a reduction in the amount of hyaluronic acid in the mucous membrane of the vagina, thus causing its moistness, elasticity and stability to decrease.

- Lactic acid/sodium lactate combined

Several factors such as oestrogen deficiency or menstruation can unfavourably affect the environment of the vagina, which is naturally acidic. This results in excessive growth of harmful bacteria and other microorganisms. The lactic acid/sodium lactate combination returns the pH of the vagina to its natural levels of 3.8–4.5 and thus reduces the risk of infection.

The active substances are naturally present in the body, so the risk of onset of side effects is very low.

The colourless and odourless ovule is simple to use and can be inserted regularly for preventative and/or therapeutic purposes, up to once daily. Premeno duo does not contain hormones.

Indications

- Premeno duo comes in vaginal ovules form for the treatment of vaginal dryness that may be the result of menopause, stress, breastfeeding or an antihormone chemotherapy, whether or not in combination with local hormone therapy.
- To support healing of damaged vaginal epithelium.
- To reduce the risk of harm to the mucous membrane due to mechanical damage. Regular use restores the correct levels of vaginal hydration, thus also improving sexual wellbeing.
- To improve defence against infections: prevention of bacterial vaginosis (infection of the vagina) and vaginal mycoses (fungal infection of the vagina).

Method of use

For the prevention and treatment of dry vaginal epithelium, this product may be used once daily to once every three days. Insertion of the ovule into the vagina is simple. The ovules should be inserted using a finger as deep as possible into the vagina. It completely dissolves there after a few minutes. Premeno duo must not be used after the expiry date (given on the pack).

Vaginal dryness resulting from oestrogen deficiency during or after the menopause:

Loading dose: Insert 1 ovule in the evening before bed for 10 consecutive days.

Maintenance treatment: for a lasting effect, insert 1 ovule every 3 days after finishing the loading dose, for as long as you consider appropriate.

Contraindications

In the event of acute or severe vaginal infection, the product should be used under the supervision of a doctor. If the patient is known to be hypersensitive to any of the ingredients, the product should not be used.

In pregnancy there are no known risks to the foetus, but because of the lack of studies on this subject, the use of the product during pregnancy cannot be recommended. Since the ovule is made from modified natural fats, condoms and diaphragms made of natural rubber should not be used in combination with Premeno duo. Polyurethane condoms can be used together with Premeno duo.

Side effects

Since the product contains lactic acid, minor skin reactions may occur in rare cases (mild burning sensation or itching), especially if the vaginal mucous membrane is very dry and/or damaged. This effect usually disappears after a short period.

Warning

Premeno duo must be kept in a dry place protected from light at 4-25°C.

Contents of pack: 10 x 2 g vaginal ovules.

Manufacturer

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Germany

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Fax +49 (0)6105 45 59 01

service@kessel-marketing.de

www.medintim.com



Please take this order form to your pharmacist.

Please supply to/order on behalf of
(Fill in/delete as appropriate)

Miss/Mrs: _____

Address: _____

Town: _____

Telephone number: _____

Premeno® duo vaginal ovules 5 mg

For the loading dose: 1 pack containing 10 units; insert 1 vaginal ovule in the evening before bed for 10 consecutive days.

For maintenance treatment: 1 pack containing 10 units; insert 1 vaginal ovule in the evening before bed, every 3 days.



Medical product CE 0124

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