PACKAGE LEAFLET: INFORMATION FOR THE USER

Dienogest León Farma 2 mg tablets

dienogest

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet:

1. What <INVENTED NAME> is and what it is used for

<INVENTED NAME> is a preparation for the treatment of endometriosis (painful symptoms due to displaced tissue of the lining of the womb). <INVENTED NAME> contains a hormone, the progestogen dienogest.

2. What you need to know before you take <INVENTED NAME>

DO NOT take <INVENTED NAME> if you:

- are suffering from a **blood clot** (thromboembolic disorder) in your veins. This may occur, for example, in the blood vessels of the legs (deep vein thrombosis) or the lungs (pulmonary embolism). See also *"<INVENTED NAME> and venous blood clots"* below
- have or have ever had a **severe arterial disease**, including cardiovascular disease, such as a **heart attack**, **stroke** or **heart disease** which causes a reduced blood supply (angina pectoris). See also *"<INVENTED NAME> and arterial blood clots"* below
- have **diabetes** with blood vessel damage
- have or have ever had **severe liver disease** (and your liver function values have not returned to normal). Symptoms of liver disease may be yellowing of the skin and/or itching of the whole body
- have or have ever had a **benign or malignant liver tumour**
- suffer or have ever suffered, or if it is suspected that you suffer from a **malignant** sex-hormone dependent tumour such as cancer of the breast or the genital organs
- have any unexplained **vaginal bleeding**
- are **allergic (hypersensitive)** to dienogest or any of the other ingredients of <INVENTED NAME> (listed in section 6 and end of Section 2)

If any of these conditions appear for the first time while using <INVENTED NAME>, stop taking it at once and consult your doctor.

Warnings and precautions
You must not use hormonal contraceptives of any form (tablet, patch, intrauterine system) while taking <INVENTED NAME>.

<INVENTED NAME> is NOT a contraceptive. If you want to prevent pregnancy, you should use condoms or other non-hormonal contraceptive precautions.

In some situations you need to take special care while using <INVENTED NAME>, and your doctor may need to examine you regularly. Tell your doctor if any of the following conditions applies to you:
If you:

- have ever had a **blood clot** (venous thromboembolism) or anyone in your immediate family has had a blood clot at a relatively early age
- have a close relative who has had **breast cancer**
- have ever suffered from **depression**
- have **high blood pressure** or develop high blood pressure while taking <INVENTED NAME>
- develop a **liver disease** while taking <INVENTED NAME>. Symptoms may include yellowing of the skin or eyes or itching all over your body. Inform your doctor also if such symptoms occurred during a previous pregnancy
- have diabetes or had **diabetes** temporarily during previous pregnancy
- have ever had **chloasma** (golden-brown patches on the skin, particularly of the face); if so, avoid too much exposure to the sun or ultraviolet radiation
- suffer from **pain in your lower abdomen** while taking <INVENTED NAME>.

While taking <INVENTED NAME> your chance of becoming pregnant is reduced because <INVENTED NAME> may affect ovulation.

If you become pregnant while taking <INVENTED NAME> you are at **a slightly increased risk** of having an extrauterine pregnancy (the embryo develops outside the womb). Tell your doctor before you start taking <INVENTED NAME>, if you had an extrauterine pregnancy in the past or have an impaired function of the Fallopian tubes.

<INVENTED NAME> and serious uterine bleeding

Uterine bleeding, for example in women with a condition where the mucous membrane of your uterus (endometrium) grows into the muscle layer of your uterus, called adenomyosis uteri or **benign tumours of the womb** sometimes called uterine fibroids (uterine leiomyomata), may become worse with the use of <INVENTED NAME>. If bleeding is heavy and continuous over time, this may lead to low red blood cell levels (anemia), which may be severe in some cases. In the event of anemia, you should discuss with your doctor if you should stop taking <INVENTED NAME>.

<INVENTED NAME> and changes in bleeding pattern

Most women treated with <INVENTED NAME> experience changes in their menstrual bleeding pattern (see section 4, possible side effects).

<INVENTED NAME> and venous blood clots

Some studies indicate that there may be a slight, but not statistically significant, increased risk of a **blood clot in the legs (venous thromboembolism)** associated with the use of preparations

with progestagens like <INVENTED NAME>. Very rarely, blood clots may cause serious permanent disabilities or may even be fatal.

The risk of a **venous blood clot** increases:

- with increasing age
- if you are overweight
- if you or one of your close relatives had a blood clot in the leg (thrombosis), lung (pulmonary embolism), or other organ at a young age
- if you must have surgery, if you have had a serious accident or if you are immobilized for a long time. It is important to tell your doctor in advance that you are using <INVENTED NAME> as the treatment may have to be stopped. Your doctor will tell you when to start <INVENTED NAME> again. This is usually about two weeks after you are back on your feet

<INVENTED NAME> and arterial blood clots

There is little evidence for an association between preparations with progestagens like <INVENTED NAME> and an increased risk of a blood clot in, for example, the bloodvessels of the heart (heart attack) or the brain (stroke). In women with hypertension the risk of stroke may be slightly enhanced by these preparations.

The risk of an **arterial blood clot** increases:

- **if you smoke. You are strongly advised to stop smoking when you use <INVENTED NAME>, especially if you are older than 35 years.**
- if you are overweight
- if one of your close relatives had a heart attack or stroke at a young age
- if you have high blood pressure

Talk to your doctor before taking <INVENTED NAME>

Stop taking <INVENTED NAME> and contact your doctor immediately if you notice possible signs of a blood clot, such as:
- severe pain and/or swelling in one of your legs
- sudden severe pain in the chest which may reach the left arm
- sudden breathlessness
- sudden cough without an obvious cause
- any unusual, severe or long-lasting headache or worsening of migraine
- partial or complete blindness or double vision
- difficulty in speaking or inability to speak
- giddiness or fainting
- weakness, strange feeling, or numbness in any part of the body

<INVENTED NAME> and cancer

It is not clear from the data currently available whether or not <INVENTED NAME> increases the risk of breast cancer. Breast cancer has been observed slightly more often in women taking hormones compared to those not taking hormones, but it is not known whether this is caused by the treatment. For example, it may be that more tumours are detected and detected earlier in women taking hormones because they are examined by their doctor more often. The occurrence of breast tumours becomes gradually less after stopping the hormone treatment. **It is important to regularly check your breasts** and you should contact your doctor if you feel any lump.

In rare cases, benign liver tumours, and in even fewer cases malignant liver tumours have been reported in women taking hormones. Contact your doctor if you have unusually severe stomach pain.

<INVENTED NAME> and osteoporosis

Changes in bone mineral density (BMD)

The use of <INVENTED NAME> may affect the strength of the bone of adolescents (12 to under 18 years). If you are under 18 your doctor will, therefore, carefully weigh the benefits and risks of using <INVENTED NAME> for you as an individual patient, taking into account possible risk factors for bone loss (osteoporosis).
If you use <INVENTED NAME>, it will help your bones if you have an adequate intake of calcium and vitamin D either via your food or via supplements.

If you have an increased risk of getting osteoporosis (weakening of bones due to loss of bone minerals), your doctor will carefully weigh the risks and benefits of treatment with <INVENTED NAME> because <INVENTED NAME> has a moderate suppressing effect on the production of oestrogen (another type of female hormone) by your body.

Other medicines and <INVENTED NAME>

Always tell your doctor which medicines or herbal products you are already using. Also tell any other doctor or dentist who prescribes another medicine (or the pharmacist) that you are taking <INVENTED NAME>.

Some medicines can have an influence on the blood levels of <INVENTED NAME> and can make it less effective, or can cause undesirable effects.
These include:

- medicines used for the treatment of
  - **epilepsy** (e.g. phenytoin, barbiturates, primidone, carbamazepine, oxcarbazepine, topiramate, felbamate)
  - **tuberculosis (**e.g. rifampicin**)**
  - **HIV and Hepatitis C Virus infections** (so called protease inhibitors and non-nucleoside reverse transcriptase inhibitors such as ritonavir, nevirapine, efavirenz)
  - **fungal infections** (griseofulvin, ketoconazole)
- the herbal remedy **St. John's** wort

Ask your doctor or pharmacist for advice before taking any medicine.

<INVENTED NAME> with food and drink
During <INVENTED NAME> treatment, you should avoid drinking grapefruit juice, because this may increase the levels of <INVENTED NAME> in your blood. This may increase the risk of getting side effects.

Laboratory tests

If you need a blood test, tell your doctor or the laboratory staff that you are taking <INVENTED NAME>, because <INVENTED NAME> can affect the results of some tests.

Pregnancy and breast-feeding

Do not take <INVENTED NAME> if you are pregnant or breast-feeding.

Driving and using machines

No effects on the ability to drive and use machines have been observed in users of <INVENTED NAME>.

<INVENTED NAME> contains lactose.

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

Children and adolescents
<INVENTED NAME> is not for use in girls before menarche (first menstrual bleeding).
The use of <INVENTED NAME> may affect the strength of the bone of adolescents (12 to under 18 years). If you are under 18 your doctor will, therefore, carefully weigh the benefits and risks of using <INVENTED NAME> for you as an individual patient, taking into account possible risk factors for bone loss (osteoporosis).

3. HOW TO TAKE <INVENTED NAME>

Always take <INVENTED NAME> exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure. For adults, the usual dose is 1 tablet per day.

The following statements apply to <INVENTED NAME> unless otherwise prescribed by your doctor. Please follow these instructions, otherwise you will not fully benefit from <INVENTED NAME>.

You can start treatment with <INVENTED NAME> on any day of your natural cycle.

Adults: take one tablet every day, preferably at the same time with some liquid as needed. When a pack is finished the next one should be started without interruption. Continue to take the tablets also on days of menstrual bleeding.

If you take more <INVENTED NAME> than you should

There have been no reports of serious harmful effects from taking too many <INVENTED NAME> tablets at one time. However, if you are concerned, contact your doctor.

If you forget to take <INVENTED NAME> or suffer from vomiting or diarrhoea

<INVENTED NAME> will be less effective if you miss a tablet. If you miss one or more tablets, take one tablet only as soon as you remember, and then continue next day taking the tablet at your usual time.

If you vomit within 3-4 hours of taking <INVENTED NAME> or you have severe diarrhoea, there is a risk that the active substance in the tablet will not be taken up by your body. The situation is almost the same as forgetting a tablet. After vomiting or diarrhoea within 3-4 hours of taking <INVENTED NAME>, you should take another tablet as soon as possible.

Do not take a double dose to make up for a forgotten tablet.

If you stop taking <INVENTED NAME>

If you stop taking <INVENTED NAME>, your original endometriosis symptoms may return.

4. POSSIBLE SIDE EFFECTS

Like all medicines, <INVENTED NAME> can cause side effects, although not everybody gets them. These effects are more common during the first months after start of intake of <INVENTED NAME> and usually disappear with continued use. You may also experience changes in your bleeding pattern, such as spotting, irregular bleeding or your periods may stop completely.

Common (affecting between 1 and 10 in every 100 users)

- weight gain
- depressed mood, problems sleeping, nervousness, loss of interest in sex, or changed mood
- headache or migraine
- nausea, abdominal pain, wind, swollen tummy or vomiting
- acne or hair loss
- back pain
- breast discomfort, ovarian cyst or hot flushes
- uterine/vaginal bleeding including spotting
- weakness or irritability

Uncommon (affecting between 1 and 10 in every 1,000 users)

- anemia
- weight loss or increase in appetite
- anxiety, depression or mood swings
- imbalance in the autonomic nervous system (controls unconscious bodily functions, e.g. perspiration) or disturbed attention
- dry eye
- tinnitus
- unspecific circulatory problems or uncommon palpitations
- low blood pressure
- shortness of breath
- diarrhoea, constipation, abdominal discomfort, inflammation of the stomach and intestines (gastrointestinal inflammation), inflammation of the gums (gingivitis)
- dry skin, excessive sweating, severe itching of the whole body, male pattern hair growth (hirsutism), brittle nails, dandruff, dermatitis, abnormal hair growth, hypersensitive response to light or problems with skin pigmentation
- pains in your bones, muscle spasms, pains and/or a sensation of heaviness in your arms and hands or legs and feet
- urinary tract infection
- vaginal thrush, dryness of the genital area, vaginal discharge, pelvic pain, atrophic inflammation of the genitals with discharge (atrophic vulvovaginitis), or a lump or lumps in the breast
- swelling due to fluid retention

Additional side effects in adolescents (12 to under 18 years): loss of bone density.

Reporting of side effects
If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the national

reporting system listed in Appendix V. By reporting side effects you can help provide more information on the safety of this medicine.

5. HOW TO STORE <INVENTED NAME>

Store in the original package to protect from light. Keep out

of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the package after "Do not use after" or "EXP." The expiry date refers to the last day of that month.

Do not throw away any medicine via wastewater or household waste. Ask your pharmacist how to throw away of medicines you no longer use. These measures will help to protect the environment.

6. CONTENTS OF THE PACK AND OTHER INFORMATION

What <INVENTED NAME> contains

The active substance is dienogest. Each tablet contains 2 mg dienogest.

The other ingredients are lactose monohydrate, maize starch, povidone K 30, vegetal magnesium stearate.

What <INVENTED NAME> looks like and contents of the pack

<INVENTED NAME> tablets are round, white tablets with a diameter of 5 mm.

They are supplied in a blister pack containing 28 tablets.

Boxes contain blister packs with
1 x 28 tablets (calendar pack)
3 x 28 tablets (calendar pack)
6 x 28 tablets (calendar pack)

Not all pack sizes may be marketed

M**arketing Authorisation Holder**

Laboratorios León Farma S.A
C/ La Vallina s/n, Polígono Industrial Navatejera
24193- Leon; Spain

Manufacturer

Laboratorios León Farma S.A
C/ La Vallina s/n, Polígono Industrial Navatejera
24193- Leon; Spain

For any information about this medicine, please contact the local representative of the Marketing Authorisation Holder:

This medicinal product is authorised in the Member States of the EEA under the following names:

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