PACKAGE LEAFLET

Package leaflet: Information for the user

Dienogest Bailleul 2 mg tabletten
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 only. Do not pass it on to others. It may harm them, even if their signs of illness 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 Dienogest Bailleul is and what it is used for
2. What you need to know before you take Dienogest Bailleul
3. How to take Dienogest Bailleul
4. Possible side effects
5. How to store Dienogest Bailleul
6. Contents of the pack and other information

1. What Dienogest Bailleul is and what it is used for

Dienogest Bailleul is a medicine for the treatment of endometriosis (painful symptoms due to displaced tissue of the lining of the womb).
This medicine contains a hormone, the progestogen dienogest.

2. What you need to know before you take Dienogest Bailleul

Do not take Dienogest Bailleul:
- if you are allergic to dienogest or any of the other ingredients of this medicine (listed in section 6).
- 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 **"Dienogest Bailleul and venous blood clots"** below
- if you 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 **"Dienogest Bailleul and arterial blood clots"** below
- if you have **diabetes** with blood vessel damage
- if you 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
- if you have or have ever had a **benign or malignant liver tumour**
- if you 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
- if you have any unexplained **vaginal bleeding**

If any of these conditions appear for the first time while using this medicine, stop taking it immediately and tell your doctor.

Warnings and precautions
You must not use hormonal contraceptives of any form (tablet, patch, intrauterine system) while taking this medicine.

This medicine 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 this medicine, 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 this medicine
- develop a **liver disease** while taking this medicine. Symptoms may include yellowing of the skin or eyes or itching all over your body. Tell 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 this medicine.

While taking this medicine your chance of becoming pregnant is reduced because this medicine may affect ovulation.

If you become pregnant while taking this medicine, 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 this medicine, if you had an extrauterine pregnancy in the past or have an impaired function of the Fallopian tubes.

Dienogest Bailleul 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 this medicine. 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 this medicine.

Dienogest Bailleul and changes in bleeding pattern
Most women treated with this medicine experience changes in their menstrual bleeding pattern (see section 4, possible side effects).

Dienogest Bailleul 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 medicines with progestagens like Dienogest Bailleul. 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 this medicine as the treatment may have to be stopped. Your doctor will tell you when to start using this medicine again. This is usually about two weeks after you are back on your feet

Dienogest Bailleul and arterial blood clots
There is little evidence for an association between medicines with progestagens like this medicine and an increased risk of a blood clot in, for example, the blood vessels of the heart (heart attack) or the brain (stroke). In women with hypertension the risk of stroke may be slightly enhanced by these medicines.
The risk of an **arterial blood clot** increases:
- **if you smoke. You are strongly advised to stop smoking when you use this medicine, 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 this medicine

Stop taking this medicine 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

Dienogest Bailleul and cancer
It is not clear from the data currently available whether or not this medicine 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.

Dienogest Bailleul and osteoporosis
Changes in bone mineral density (BMD)
The use of this medicine 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 this

medicine for you as an individual patient, taking into account possible risk factors for bone loss (osteoporosis).

If you use this medicine, it will help your bones if you have an adequate intake of calcium and vitamin D either from your food or from 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 this medicine because this medicine has a moderate suppressing effect on the production of oestrogen (another type of female hormone) by your body.

Other medicines and Dienogest Bailleul
Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. This includes herbal medicines and other medicines you've bought without a prescription. Also tell any other doctor or dentist who prescribes another medicine (or the pharmacist) that you are taking Dienogest Bailleul.

Some medicines can have an influence on the blood levels of Dienogest Bailleul and can make it less effective or can cause undesirable effects.
These include:
- medicines used for the treatment of:
    - **epilepsy** (for example phenytoin, barbiturates, primidone, carbamazepine, oxcarbazepine, topiramate, felbamate)
    - **tuberculosis** (for example 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.

Dienogest Bailleul with food and drink
During treatment with this medicine, you should avoid drinking grapefruit juice, because this may increase the levels of Dienogest Bailleul 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 this medicine, because this medicine can affect the results of some tests.

Pregnancy and breast-feeding
Do not take this medicine 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 this medicine.

Children and adolescents
This medicine is not for use in girls before menarche (first menstrual bleeding).
The use of Dienogest Bailleul 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 Dienogest Bailleul for you as an individual patient, taking into account possible risk factors for bone loss (osteoporosis).

Dienogest Bailleul 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.

3. How to take Dienogest Bailleul

Always take this medicine exactly as your doctor has told you. 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 this medicine unless otherwise prescribed by your doctor. Please follow these instructions, otherwise you will not fully benefit from this medicine.

You can start treatment with this medicine 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 Dienogest Bailleul than you should
There have been no reports of serious harmful effects from taking too many tablets of this medicine at one time. However, if you are concerned, contact your doctor.

If you forget to take Dienogest Bailleul or suffer from vomiting or diarrhoea
This medicine 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 this medicine 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 this medicine, 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 Dienogest Bailleul
If you stop taking this medicine, your original endometriosis symptoms may return.

If you have any further questions on the use of this medicine, ask your doctor of pharmacist.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them. These effects are more common during the first months after start of intake of this medicine 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 (may affect up to 1 in 10 people)
- 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 (may affect up to 1 in 100 people)
- anemia
- weight loss or increase in appetite
- anxiety, depression or mood swings
- imbalance in the autonomic nervous system (controls unconscious bodily functions, such as 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 Dienogest Bailleul

Keep this medicine out of the sight and reach of children.

Store in the original package in order to protect from light.

Do not use this medicine after the expiry date which is stated on the packaging after “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 medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Dienogest Bailleul contains
- The active substance is dienogest. Each tablet contains 2 mg dienogest.
- The other ingredients are lactose monohydrate, cellulose microcrystalline, potato starch, povidone K-25, talc, crospovidone (Type A), magnesium stearate.

What Dienogest Bailleul looks like and contents of the pack
Dienogest Bailleul are white to off-white, round, flat faced beveled edge tablets debossed with "NC" on one side and "22" on other side with a diameter of around 7 mm.

The tablets are packed in blisters of green PVC/PVDC-film and Aluminium foil film containing 14 tablets each.

Carton boxes with 28, 84 or 168 tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Laboratoires Bailleul S.A.
14-16 Avenue Pasteur
L-2310 Luxembourg
LUXEMBURG

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

France: Dienogest Bailleul 2 mg, comprimé
Italy: Elyora 2 mg compresse
Spain: Agestin 2mg comprimidos EFG

Deze bijsluiter is voor het laatst goedgekeurd in januari 2026