

**Package leaflet: Information for the user**

**Raener 2mg/0.03 mg film-coated tablets**

ethinylestradiol and dienogest

**Important things to know about combined hormonal contraceptives (CHCs):**

- They are one of the most reliable reversible methods of contraception if used correctly
- They slightly increase the risk of having a blood clot in the veins and arteries, especially in the first year or when restarting a combined hormonal contraceptive following a break of 4 or more weeks
- Please be alert and see your doctor if you think you may have symptoms of a blood clot (see section 2 “Blood clots”)

**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,.
- 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 Raener 2mg/0.03 mg is and what it is used for
2. What you need to know before you take Raener 2mg/0.03 mg
3. How to take Raener 2mg/0.03 mg
4. Possible side effects
5. How to store Raener 2mg/0.03 mg
6. Contents of the pack and other information

**1. What Raener 2mg/0.03 mg is and what it is used for**

Raener 2mg/0.03 mg is a medicinal product used to

- prevent pregnancy (contraceptive “pill”).
- treatment of women with moderately severe acne, who agree to receive a contraceptive pill after failure of suitable local or oral antibiotic treatments.

It contains a small amount of female hormones progesterone namely (dienogest) and an estrogen (ethinylestradiol).Raener 2mg/0.03 mg

Contraceptive pills that contain two hormones are called “combination” pills or combined oral contraceptives.

Oral (orally administered) contraceptive pills are a very effective method of family planning. If taken regularly (without omitting tablets), the possibility of becoming pregnant is very low.

In women with increased male hormonal effect, the “androgenic effect” results in the development of acne, these symptoms got better upon application of Raener 2mg/0.03 mg.

## 2. What you need to know before you take Raener 2mg/0.03 mg

### General notes

Before you start using Raener 2mg/0.03 mg you should read the information on blood clots in section 2. It is particularly important to read the symptoms of a blood clot – see Section 2 “Blood clots”.

Before you can begin taking Raener 2mg/0.03 mg, your doctor will ask you some questions about your personal health history and that of your close relatives. The doctor will also measure your blood pressure and, depending upon your personal situation, may also carry out some other tests.

In this leaflet, several situations are described where you should stop using Raener 2mg/0.03 mg, or where the reliability of Raener 2mg/0.03 mg may be decreased. In such situations you should either not have sex or you should take extra non hormonal contraceptive precautions, for example, use a condom or another barrier method. Do not use the calendar or temperature methods. These methods can be unreliable as Raener 2mg/0.03 mg alters the monthly changes of body temperature and of cervical mucus.

Raener 2mg/0.03 mg like other hormonal contraceptives, Raener 2mg/0.03 mg does not protect you against HIV-infection (AIDS) or other sexually transmitted disease.

If you have acne, you should experience an improvement, normally after 3 to 6 months of treatment, and it is even possible to experience yet another improvement after 6 months of intake. You should talk to your doctor within 3 to 6 months after starting the treatment, and afterwards have check-ups at regular intervals to assess the need for extending the treatment

### Do not take Raener 2mg/0.03 mg

You must not use Raener 2mg/0.03 mg if you have any of the conditions listed below. If you do have any of the conditions listed below, you must tell your doctor. Your doctor will discuss with you what other form of birth control would be more appropriate.

- If you are allergic to ethinylestradiol, dienogest or another ingredient of this medicine (listed in section 6). Allergy may be manifested, for example, by itching, rash or swelling.
- if you have (or have ever had) a blood clot in a blood vessel of your legs (deep vein thrombosis, DVT), your lungs (pulmonary embolus, PE) or other organs;
- if you know you have a disorder affecting your blood clotting – for instance, protein C deficiency, protein S deficiency, antithrombin-III deficiency, Factor V Leiden or antiphospholipid antibodies;
- if you need an operation or if you are off your feet for a long time (see section ‘Blood clots’);

- if you have ever had a heart attack or a stroke;
- if you have (or have ever had) angina pectoris (a condition that causes severe chest pain and may be a first sign of a heart attack) or transient ischaemic attack (TIA – temporary stroke symptoms);
- if you have any of the following diseases that may increase your risk of a clot in the arteries:
  - severe diabetes with blood vessel damage
  - very high blood pressure
  - a very high level of fat in the blood (cholesterol or triglycerides)
  - a condition known as hyperhomocysteinaemia
- if you have (or have ever had) a type of migraine called ‘migraine with aura’;
- If you smoke.
- If you have or have ever had tumour affected by sexual hormones. (for example breast or genital organs)
- If you have or have ever had a benign or malignant liver tumour
- If you have or have ever had liver diseases, if the liver values in the blood have not normalized (also in case of Dubin-Johnson and Rotor Syndrome). If you have or have ever had liver tumours (benign or malign).
- If you have any vaginal bleeding of unknown origin;
- if you are pregnant or suspect you may be pregnant;
- if you have hepatitis C and are taking the medicinal products containing ombitasvir/paritaprevir/ritonavir and dasabuvir, glecaprevir / pibrentasvir or sofosbuvir/velpatasvir/voxilaprevir (see also in section Other medicines and Raener 2mg/0.03 mg).

If you get any of the above conditions for the first time while you are taking the pill, you must stop taking the product immediately and consult your doctor. In the meantime, you should use a different, non-hormonal method of contraception. See also “General notes” in the next section.

### **Additional information about the special user groups**

#### *Children and adolescents*

Raener 2mg/0.03 mg) is not intended for women (girls) who are not yet having menstruation.

#### *Use in older women*

Raener 2mg/0.03 mg) is not intended for postmenopausal women.

#### *Hepatic impairment*

Do not take Raener 2mg/0.03 mg) if you have liver disease. See also "Do not take Raener 2mg/0.03 mg) “ and "Warnings and precautions“.

#### *Renal impairment*

Consult a doctor. The available data do not indicate a need to change the use of Raener 2mg/0.03 mg)

### **Warnings and precautions**

**When to take special care with Raener 2mg/0.03 mg.**

When should you contact your doctor?

Seek urgent medical attention

- 0 if you notice possible signs of a blood clot that may mean you are suffering from a blood clot in the leg (i.e. deep vein thrombosis), a blood clot in the lung (i.e. pulmonary embolism), a heart attack or a stroke (see 'Blood clot' (thrombosis) section below.

For a description of the symptoms of these serious side effects please go to "How to recognise a blood clot".

If the combined pill is used by a woman who is also experiencing any of the conditions listed below, the user may need to be monitored more closely.

**Tell your doctor if any of the following conditions apply to you.**

If the condition develops, or gets worse while you are using Raener 2mg/0.03 mg, you should also tell your doctor.

- if you smoke
- if you have diabetes mellitus;
- if you are overweight;
- if you have hypertension;
- if you have Crohn's disease or ulcerative colitis (chronic inflammatory bowel disease);
- if you have systemic lupus erythematosus (SLE –; a disease affecting your natural defense system);
- if you have haemolytic uraemic syndrome (HUS - a blood clotting disorder causing failure of the kidneys);
- if you have sickle cell anaemia (an inherited disease of the red blood cells);
- if you have elevated levels of fat in the blood (hypertriglyceridaemia) or a positive family history for this condition. Hypertriglyceridaemia has been associated with an increased risk of developing pancreatitis (inflammation of the pancreas);
- if you need an operation, or you are off your feet for a long time (see in section 2 'Blood clots');
- if you have just given birth you are at an increased risk of blood clots. You should ask your doctor how soon after delivery you can start taking Raener 2mg/0.03 mg;
- If you have an inflammation in the veins under the skin (superficial thrombophlebitis);
- If you have varicose veins.
- if you have valvular heart disease or cardiac rhythm disorders;
- if somebody of your immediate relatives has had a blood clot (thrombosis in the lower limb,

DIENOGEST 2 MG + ETHINYLESTRADIOL 0.03 MG FILM-COATED TABLET

in the lung - pulmonary embolism or elsewhere), a heart attack or a stroke at a younger age;

- if you have migraine;
  - if you have epilepsy (see "Other medicines and Raener 2mg/0.03 mg");
  - if a close relative has had breast cancer;
  - if you have liver or gall bladder disease
  - if you have or have had conditions that first appeared or worsened during pregnancy or earlier use of sex hormones (for example, hearing loss, a blood disease called porphyria, skin rash with blisters during pregnancy called gestational herpes, a nerve disease called Sydenham's chorea);
  - if you have yellow-brown patches on your skin, especially on the face (chloasma), if so, avoid exposure to the sun or ultraviolet radiation;
  - If you experience symptoms of angioedema such as swollen face, tongue and/or throat and/or difficulty swallowing or hives potentially with difficulty breathing contact a doctor immediately. Products containing estrogens may cause or worsen the symptoms of hereditary and acquired angioedema
- If any of these conditions or diseases first appear, reappear or worsen while you are taking the pill, contact your doctor.

## BLOOD CLOTS

Using a combined hormonal contraceptive such as Raener 2mg/0.03 mg increases your risk of developing a blood clot compared with not using one. In rare cases a blood clot can block blood vessels and cause serious problems.

Blood clots can develop

- in veins (referred to as a 'venous thrombosis', 'venous thromboembolism' or VTE)
- in the arteries (referred to as an 'arterial thrombosis', 'arterial thromboembolism' or ATE).

Recovery from blood clots is not always complete. Rarely, there may be serious lasting effects or, very rarely, they may be fatal.

**It is important to remember that the overall risk of a harmful blood clot due to Raener 2mg/0.03 mg is small.**

## HOW TO RECOGNISE A BLOOD CLOT

Seek urgent medical attention if you notice any of the following signs or symptoms.

Are you experiencing any of these signs?	What are you possibly suffering from?
<ul style="list-style-type: none"><li>• swelling of one leg or along a vein in the leg or foot especially when accompanied by:</li></ul>	Deep vein thrombosis

DIENOGEST 2 MG + ETHINYLESTRADIOL 0.03 MG FILM-COATED TABLET

<ul style="list-style-type: none"> <li>• pain or tenderness in the leg which may be felt only when standing or walking</li> <li>• increased warmth in the affected leg</li> <li>• change in colour of the skin on the leg e.g. turning pale, red or blue</li> </ul>	
<ul style="list-style-type: none"> <li>• sudden unexplained breathlessness or rapid breathing;</li> <li>• sudden cough without an obvious cause, which may bring up blood;</li> <li>• sharp chest pain which may increase with deep breathing;</li> <li>• severe light headedness or dizziness;</li> <li>• rapid or irregular heartbeat</li> <li>• severe pain in your stomach;</li> </ul> <p>If you are unsure, talk to a doctor as some of these symptoms such as coughing or being short of breath may be mistaken for a milder condition such as a respiratory tract infection (e.g. a 'common cold').</p>	<p>Pulmonary embolism</p>
<p>Symptoms most commonly occur in one eye:</p> <ul style="list-style-type: none"> <li>• immediate loss of vision or</li> <li>• painless blurring of vision which can progress to loss of vision</li> </ul>	<p>Retinal vein thrombosis (blood clot in the eye)</p>
<ul style="list-style-type: none"> <li>• chest pain, discomfort, pressure, heaviness</li> <li>• sensation of squeezing or fullness in the chest, arm or below the breastbone;</li> <li>• fullness, indigestion or choking feeling;</li> <li>• upper body discomfort radiating to the back, jaw, throat, arm and stomach;</li> <li>• sweating, nausea, vomiting or dizziness;</li> <li>• extreme weakness, anxiety, or shortness of breath;</li> <li>• rapid or irregular heartbeats</li> </ul>	<p>Heart attack</p>
<ul style="list-style-type: none"> <li>• sudden weakness or numbness of the face, arm or leg, especially on one side of the body;</li> <li>• sudden confusion, trouble speaking or understanding;</li> <li>• sudden trouble seeing in one or both eyes;</li> </ul>	<p>Stroke</p>

<ul style="list-style-type: none"> <li>• sudden trouble walking, dizziness, loss of balance or coordination;</li> <li>• sudden, severe or prolonged headache with no known cause;</li> <li>• loss of consciousness or fainting with or without seizure.</li> </ul> <p>Sometimes the symptoms of stroke can be brief with an almost immediate and full recovery, but you should still seek urgent medical attention as you may be at risk of another stroke.</p>	
<ul style="list-style-type: none"> <li>• swelling and slight blue discolouration of an extremity;</li> <li>• severe pain in your stomach (acute abdomen)</li> </ul>	<p>Blood clots blocking other blood vessels</p>

## BLOOD CLOTS IN A VEIN

### What can happen if a blood clot forms in a vein?

- The use of combined hormonal contraceptives has been connected with an increase in the risk of blood clots in the vein (venous thromboembolism). However, these side effects are rare. Most frequently, they occur in the first year of use of a combined hormonal contraceptive.
- If a blood clot forms in a vein in the leg or foot it can cause a deep vein thrombosis (DVT).
- If a blood clot travels from the leg and lodges in the lung it can cause a pulmonary embolism.
- Very rarely a clot may form in a vein in another organ such as the eye (retinal vein thrombosis).

### When is the risk of developing a blood clot in a vein highest?

The risk of developing a blood clot in a vein is highest during the first year of taking a combined hormonal contraceptive. The risk may also be higher if you restart taking a combined hormonal contraceptive (the same product or a different product) after a break of 4 weeks or more

After the first year, the risk gets smaller but is always slightly higher than if you were not using a combined hormonal contraceptive.

When you stop Raener 2mg/0.03 mg your risk of a blood clot returns to normal within a few weeks.

### What is the risk of developing a blood clot?

The risk depends on your natural risk of VTE and the type of combined hormonal contraceptive you are taking.

The overall risk of a blood clot in the leg or lung (DVT or PE) with Raener 2mg/0.03 mg is small.

- 0 Out of 10,000 women who are not using any combined hormonal contraceptive and are not pregnant, about 2 will develop a blood clot in a year.

DIENOGEST 2 MG + ETHINYLESTRADIOL 0.03 MG FILM-COATED TABLET

- 0 Out of 10,000 women who are using a combined hormonal contraceptive that contains levonorgestrel, norethisterone, or norgestimate about 5-7 will develop a blood clot in a year.
- 0 Out of 10,000 women who are using a combined hormonal contraceptive that contains dienogest and ethinylestradiol such as Jeanine between about 8 and 11 women will develop a blood clot in a year.
- 0 The risk of having a blood clot will vary according to your personal medical history (see “Factors that increase your risk of a blood clot” below)

	<b>Risk of developing a blood clot in a year</b>
Women who are <b>not using</b> a combined hormonal pill/patch/ring and are not pregnant	About 2 out of 10,000 women
Women using a combined hormonal contraceptive pill containing <b>levonorgestrel, norethisterone or norgestimate</b>	About 5-7 out of 10,000 women
Women using Raener 2mg/0.03 mg	About 8-11 out of 10,000 women

**Factors that increase your risk of a blood clot in a vein**

The risk of a blood clot with Raener 2mg/0.03 mg is small but some conditions will increase the risk. Your risk is higher:

- if you are very overweight (body mass index or BMI over 30kg/m<sup>2</sup>);
- if one of your immediate family has had a blood clot in the leg, lung or other organ at a young age (e.g. below the age of about 50). In this case you could have a hereditary blood clotting disorder;
- if you need to have an operation, or if you are off your feet for a long time because of an injury or illness, or you have your leg in a cast. The use of Raener 2mg/0.03 mg may need to be stopped several weeks before surgery or while you are less mobile. If you need to stop Raener 2mg/0.03 mg ask your doctor when you can start using it again.
- as you get older (particularly above about 35 years);
- if you gave birth less than a few weeks ago

The risk of developing a blood clot increases the more conditions you have.

Air travel (>4 hours) may temporarily increase your risk of a blood clot, particularly if you have some of the other factors listed.

It is important to tell your doctor if any of these conditions apply to you, even if you are unsure. Your doctor may decide that Raener 2mg/0.03 mg needs to be stopped.

If any of the above conditions change while you are using Raener 2mg/0.03 mg, for example a close family member experiences a thrombosis for no known reason; or you gain a lot of weight, tell your doctor.

## **BLOOD CLOTS IN AN ARTERY**

### **What can happen if a blood clot forms in an artery?**

Like a blood clot in a vein, a clot in an artery can cause serious problems. For example, it can cause a heart attack or a stroke.

### **Factors that increase your risk of a blood clot in an artery**

It is important to note that the risk of a heart attack or stroke from using Raener 2mg/0.03 mg is very small but can increase:

- with increasing age (beyond about 35 years);
- **if you smoke.** When using a combined hormonal contraceptive like Raener 2mg/0.03 mg you are advised to stop smoking. If you are unable to stop smoking and are older than 35 your doctor may advise you to use a different type of contraceptive;
- if you are overweight;
- if you have high blood pressure;
- if a member of your immediate family has had a heart attack or stroke at a young age (under 50). In this case you could also have a higher risk of having a heart attack or stroke;
- if you, or someone in your immediate family, have a high level of fat in the blood (cholesterol or triglycerides);
- if you get migraines, especially migraines with aura;
- if you have a problem with your heart (valve disorder, disturbance of the rhythm called atrial fibrillation)
- if you have diabetes.

If you have more than one of these conditions or if any of them are particularly severe the risk of developing a blood clot may be increased even more.

If any of the above conditions change while you are using Raener 2mg/0.03 mg, for example you start smoking, a close family member experiences a thrombosis for no known reason; or you gain a lot of weight, tell your doctor.

### **The 'pill' and cancer**

**Breast cancer** has been observed slightly more often in women using combination pills, but it is not known whether this is caused by the treatment. The findings could be due to the fact that women taking the combined pill were examined by the doctor much more often. The risk of breast cancer gradually decreases after stopping the combined hormonal contraceptive.. 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 pill users. These tumours can cause occasionally lead to life-threatening internal bleeding. Contact your doctor immediately if you have severe abdominal pain.

The most important risk factor for **cervical cancer** is persistent human papilloma virus (HPV) infection.

Some studies suggest that long-term use of hormonal contraception is a risk factor for developing cervical cancer in women. However, it is not clear to what extent this risk is increased by sexual behavior or other factors such as human papilloma virus.

**The above mentioned tumors can cause a life-threatening condition or death.**

### **Psychiatric disorders**

- Some women using hormonal contraceptives including < Raener 2mg/0.03 mg have reported depression or depressed mood. Depression can be serious and may sometimes lead to suicidal thoughts. If you experience mood changes and depressive symptoms contact your doctor for further medical advice as soon as possible.

### **Bleeding between periods**

During the first few months that you are taking Raener 2mg/0.03 mg, you may have unexpected bleeding or spotting between regular periods. You may also need hygiene products and take the tablets as usual. Irregular bleeding usually disappears as soon as your body gets used to the pill (usually after 3 months of use).

Contact your doctor if this bleeding occurs for more than a few months, or if it reappears after disappearing.

### **What you must do if no bleeding occurs during the tablet-free interval**

If you have taken the tablets correctly, you have not had vomiting or severe diarrhoea and you have not taken any other medicines, it is highly unlikely that you are pregnant. Continue to take Raener 2mg/0.03 mg as usual.

If you did not take the tablets correctly before the first missed withdrawal bleeding or if you do not have the withdrawal bleeding two times in a row, you could be pregnant. Contact your doctor immediately. Only start the next strip if you are sure that you are not pregnant. In the meantime, use non-hormonal contraceptives (see also: "General notes").

### **Other medicines and Raener 2mg/0.03 mg**

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 use Jeanine. They can tell you if you need to take additional contraceptive precautions (for example condoms) and if so, for how long, or whether the use of another medicine you need must be changed.

Some medicines

- can have an influence on the blood levels of Raener 2mg/0.03 mg
- can make it **less effective in preventing pregnancy**,
- can cause unexpected bleeding.

These include medicines used for the treatment of:

- epilepsy, (e.g. phenytoin, barbiturates, primidone, carbamazepine, oxcarbazepine, topiramate and felbamate);
- tuberculosis (for example rifampicin),
- HIV and Hepatitis C infections (so-called protease inhibitors and non-nucleoside reverse transcriptase inhibitors such as ritonavir, nevirapine, efavirenz).
- fungal infections (e.g. griseofulvin,azole antifungals such as itraconazole, voriconazole, fluconazole)
- bacterial infections (macrolide antibiotics, e. g. clarithromycin, erythromycin);
- certain heart conditions, high blood pressure (calcium channel blockers, e. g. verapamil, diltiazem)
- joint diseases: arthritis, arthrosis (etoricoxib)
- herbal supplements containing St. John's Wort (*Hypericum perforatum*).
- grapefruit juice

**influence the efficacy of other medicines, e.g.**

- lamotrigine
- cyclosporin
- melatonin
- midazolam
- theophyllin

Do not use Raener 2mg/0.03 mg if you have Hepatitis C and are taking the medicinal products containing ombitasvir/paritaprevir/ritonavir and dasabuvir, glecaprevir / pibrentasvir or sofosbuvir/velpatasvir/voxilapreviras this may cause increases in liver function blood test results (increase in ALT liver enzyme).

Your doctor will prescribe another type of contraceptive prior to start of the treatment with these medicinal products.

Raener 2mg/0.03 mg can be restarted approximately 2 weeks after completion of this treatment. See section "Do not use Raener 2mg/0.03 mg".

*Ask your doctor or pharmacist for advice before taking any medicine. Talk to your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. They may advise you on extra protective measures while you are taking other medication together with Raener 2mg/0.03 mg.*

**Laboratory tests**

If you need a blood test, tell the doctor or laboratory staff that you are taking an oral contraceptive because this medicine can affect the results of some tests

**Pregnancy, breast-feeding and fertility**

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist before taking this medicine.

### **Pregnancy**

If you are pregnant or think you may be pregnant or are planning to have a baby, do not take Raener 2mg/0.03 mg. If pregnancy develops while taking Raener 2mg/0.03 mg, the pill should be withdrawn immediately and contact your doctor. . If you want to become pregnant, you can stop taking Raener 2mg/0.03 mg at any time (see also “If you want to stop taking Raener 2mg/0.03 mg ”

### **Breast-feeding**

Use of Raener 2mg/0.03 mg is generally not advisable when a woman is breast-feeding. If you want to take the pill while you are breast-feeding you should contact your doctor.

### **Driving and using machines**

No studies on the effect on the ability to drive and operation of machines have been performed.

### **Raener 2mg/0.03 mg contains lactose**

This medicine 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 Raener 2mg/0.03 mg**

Always take Raener 2mg/0.03 mg exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

Each blister of Raener 2mg/0.03 mg contains 21 film-coated tablets. Next to each tablet is printed the day of the week that it should be taken. Take the tablet at about the same time each day; with the required amount of fluid. Follow the direction of the arrows every day until all 21 tablets have been taken. You will not take any tablets during the next 7 days. Menstruation (withdrawal bleeding) should occur during these 7 days. This usually starts 2 to 3 days after you take the last Raener 2mg/0.03 mg tablet

Start a new blister pack on the 8<sup>th</sup> day, whether your bleeding has stopped or not. This means that you should start every blister pack on the same day of the week, and that the withdrawal bleed should occur on around the same day every month.

With proper use of combined oral contraceptives, their failure is about 1% per year. If a tablet is missed or is taken incorrectly during use, the frequency of failure may increase.

### **When to start taking Raener 2mg/0.03 mg**

#### **If you have not taken any contraceptive ‘pills’ during the previous month:**

One film-coated tablet, starting on the first day of the menstrual cycle (the first day of menstruation as Day 1), by taking the pill marked with the correct day of the week from the blister. Continue the next days in the correct order. This is how Raener 2mg/0.03 mg works immediately and there is no need to use any other contraceptive method.

If you start taking Raener 2mg/0.03 mg between day 2 and 5, use an additional barrier contraception during the first 7 days of taking the ‘pill’.

### **Changing from a combined hormonal contraceptive, or combined contraceptive vaginal ring or patch**

You can start taking Raener 2mg/0.03 mg on the day after you take the last pill from the strip of your previous contraceptive (that means that there will be no interval without tablet taking). If your previous package also contained tablets without active ingredients (inactive tablets), you can start taking Raener 2mg/0.03 mg on the day after taking the last active tablet (if you are not sure if the tablets are active, ask your doctor or pharmacist). You can start taking it later, but at the latest on the day after the tablet-free days of your previous pill finish (or after taking the last inactive tablet of your previous pill). In the case of a patch or vaginal ring, you should start taking Raener 2mg/0.03 mg preferably on the day they are removed and at the latest on the day they should be re-applied.

If you will follow these instructions, you do not need to use any other contraceptive method.

**Changing from a progestogen-only method (from a progestogen-only pill, injection, implant or progestogen-releasing intrauterine system)**

You can stop taking the mini- pills at any time, and start taking Raener 2mg/0.03 mg the next day at the usual time. However, if you have intercourse, use an additional contraceptive method (barrier method) during the first 7 days of use

From an injectable, an implant or IUS, start taking Raener 2mg/0.03 mg on the day in which you should have normally been receiving the next injection or on the day in which the implant or the IUD is removed. However, if you have intercourse, use an additional contraceptive method (barrier method) during the first 7 days of taking the tablets.

Raener 2mg/0.03 mg

**After having a baby**

If you have just had a baby, your doctor may advise you to start taking Raener 2mg/0.03 mg after your first period. However in some cases you can start hormonal contraception earlier, please ask your doctor. If, after having a baby, you have had intercourse before starting Raener 2mg/0.03 mg, you must first be sure that you are not pregnant or you must wait until the next menstrual bleed.

If you are breast-feeding and you want to start taking Raener 2mg/0.03 mg, talk to your doctor.

**After abortion or miscarriage**

Talk to your doctor about taking Raener 2mg/0.03 mg

**If you take more Raener 2mg/0.03 mg than you should:**

There are no reports of serious harmful results of taking too many Raener 2mg/0.03 mg tablets.

If you take several tablets at once then you may have symptoms of nausea, vomiting or vaginal bleeding. Even young girls who have not yet menstruated but have inadvertently taken this medicine may experience this bleeding.

If you discover that a child has taken Raener 2mg/0.03 mg, ask your doctor for advice.

**If you forget to take Raener 2mg/0.03 mg**

Depending on the day of the cycle in which **one** tablet has been missed, **additional contraceptive measures** may be required, like a barrier method such as a condom. **Take the tablets as described below.** See the diagram below for details. If in doubt, contact your doctor.

- If less **than 12 hours** have passed since you were supposed to take the tablet, the reliability of the pill is maintained. Take the forgotten tablet as soon as possible and then continue to take the following tablets at the usual times.
- If you are **more than 12 hours** late taking a tablet, the protection against pregnancy may be reduced. The more consecutive tablets you miss, the greater the risk of becoming pregnant. There is a particularly high risk of becoming pregnant if you miss a tablet at the beginning or at the end of the strip. Therefore, you should keep the following rules (see also the diagram for missed tablets below)
- **More than one tablet missed**  
Contact your doctor.

**Do not take more than 2 tablets in one day to replace a missed tablet.**

If you have missed tablets and then do not get a withdrawal bleeding in the first normal tablet-free interval, the possibility of pregnancy must be considered. In this case you must talk to your doctor before you start the next pack.

Follow the instructions below if you have forgotten to take a tablet:

**If you forgot 1 tablet in week 1:**

If you forget to start taking a new pack or if you forget to take your tablet within the first 7 days, there is a risk that you may be pregnant (if you have had intercourse within 7 days before you miss a tablet). Contact your doctor before taking a new pack. See also diagram below.

If you have not had intercourse before missing the tablet, take the missed tablet as soon as you remember (even if this means taking two tablets at the same time) and take the next tablet at the usual time. Take additional contraceptive precautions (barrier method-condom) for the next 7 days.

**If you forgot 1 tablet in week 2**

Take the missed tablet as soon as you remember (even if this means taking two tablets at the same time) and take the next tablet at the usual time. The reliability of the pill is maintained, and you do not need to use additional contraceptive

**If you forgot 1 tablet in week 3:**

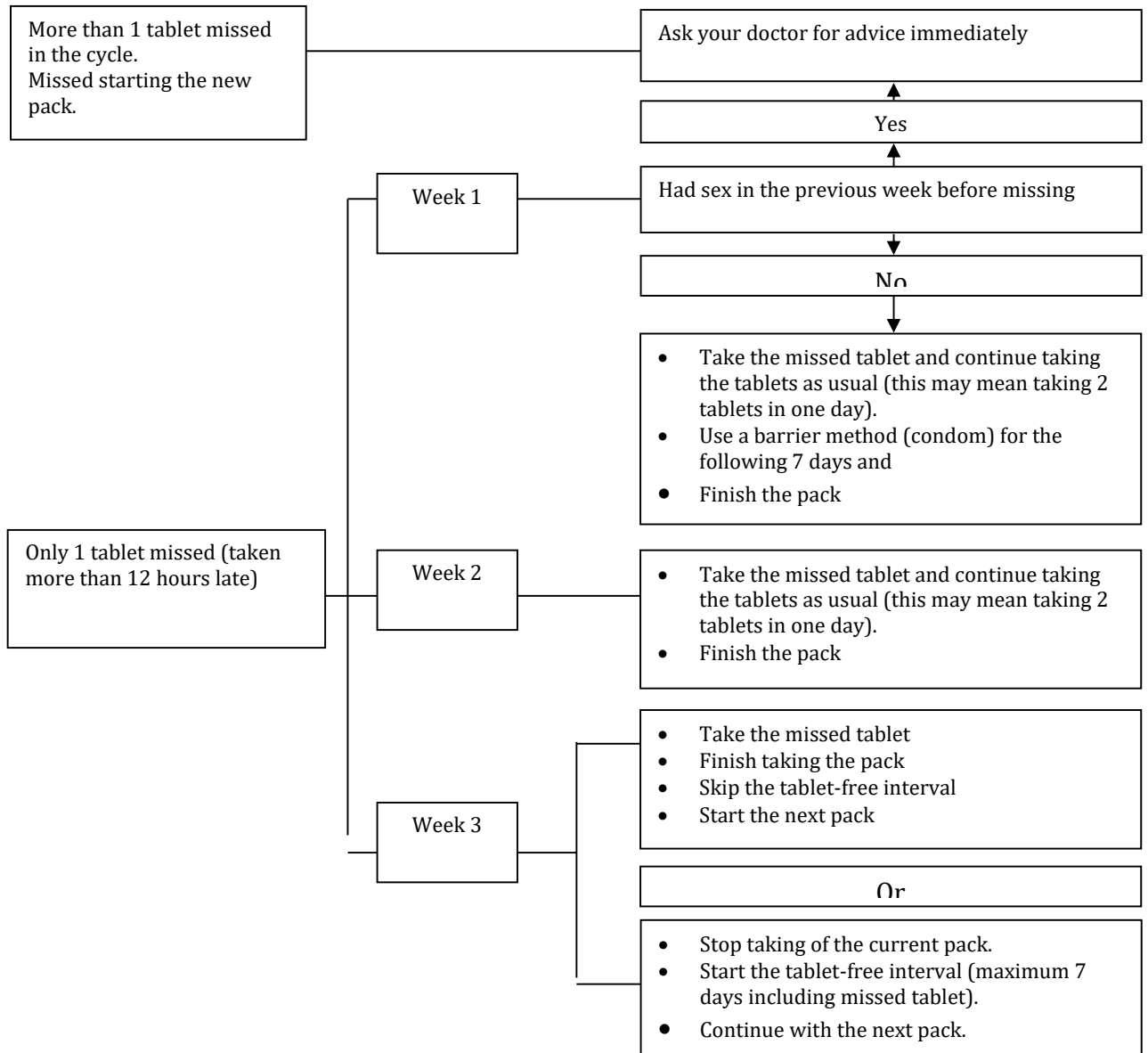
If you follow one of the two procedures explained below, there is no need for additional contraceptive measures:

**Option 1:** Take the missed tablet as soon as you remember (even if this means taking two tablets at the same time). Thereafter, you should continue taking the tablets at the usual time. You should then start the next pack immediately after taking the last tablet in the current pack, i.e. **without a tablet-free interval between the packs**. Withdrawal bleeding is unlikely until the end of the second pack, but there may be some spotting, or breakthrough bleeding, on the days you are taking tablets.

or

**Option 2:** You may also stop taking tablets from the current pack. In that case, you should keep a period without tablets of up to 7 days, **including the day you forgot the tablet**, and thereafter continue with tablets from next pack.

**Diagram for missed tablets procedure**



**If you vomit or have severe diarrhoea**

If you have digestive disturbances, such as vomiting, or diarrhoea within 4 hours after taking a tablet, the active ingredient may not be fully absorbed in your body. In these cases, follow the instructions that apply if you forgot to take a tablet and noticed it within 12 hours. If you do not want to deviate from your normal rhythm, take a replacement tablet from another blister pack. If the gastro-intestinal symptoms persist for several days or are recurrent, use a barrier contraception method (for example condom) and inform your doctor.

**If you stop taking Raener 2mg/0.03 mg**

You can stop taking Raener 2mg/0.03 mg at any time. If you do not want to become pregnant, ask your doctor about other reliable contraceptive methods.

If you stop taking Raener 2mg/0.03 mg because you want to get pregnant, it is generally recommended that you wait until you have had a natural period before trying to get pregnant. In this way, you will be able to calculate the expected delivery date more easily.

**If you want to delay the withdrawal bleeding (your period)**

If you want to delay your period, you should continue the next blister pack of Raener 2mg/0.03 mg immediately after taking the last tablet in the current pack. You can take as many pills from this next pack as you want, until the end of the second blister pack. If you want the bleeding to start, just stop taking it. When you use the second pack, you may have breakthrough bleeding or spotting. Regular intake of Raener 2mg/0.03 mg is resumed after the usual 7 day tablet-free interval.

**If you want to change the first day of your period**

If you take the tablets according to the instructions, you will always have your monthly period on approximately the same days every four weeks. If you have to change this day, you may shorten (but never lengthen) the forthcoming tablet-free interval by as many days as you like. For example, if your monthly period usually starts on Friday and you want it to start on Tuesday (i.e. 3 days earlier), you should start the next pack three days earlier than usual. The shorter the pill-free interval (i.e. 3 days or less), the greater the possibility that you will not have a withdrawal bleeding, and that you may have breakthrough bleeding or spotting during the next pack.

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

**4. Possible side effects**

Like all medicines, this medicine can have side effects, although not everybody gets them. If any of the side effects get serious, or if you notice any side effects not listed in this leaflet, please tell your doctor.

An increased risk of blood clots in your veins (venous thromboembolism (VTE)) or blood clots in your arteries (arterial thromboembolism (ATE)) is present for all women taking combined hormonal contraceptives. For more detailed information, please, see section 2 "What you need to know before you use Raener 2mg/0.03 mg".

**Serious side effects**

The serious reactions associated with the use of the pill as well as the associated symptoms are described in the sections: "What you need to know before you take Raener 2mg/0.03 mg", "Blood clots", "Pill and Cancer".

Please read these sections of the package leaflet for detailed information and contact your doctor if necessary.

Contact a doctor immediately if you experience any of the following symptoms of angioedema: swollen face, tongue and/or throat and/or difficulty swallowing or hives potentially with difficulty breathing (see also section "Warnings and precautions").

### Other possible side effects

The following is a list of the side effects that have been reported in studies with dienogest /ethinylestradiol:

**Common** (between 1 and 10 in every 100 users may be affected):

- Headaches
- Chest pain, including chest discomfort and breast tenderness

**Uncommon** (between 1 and 10 in every 1,000 users may be affected): Inflammation of the genitals (vaginitis / vulvovaginitis), vaginal yeast infections (candidiasis, vulvovaginal infections)

- Increase in appetite
- Depressed mood
- Vertigo
- Migraine
- High or low blood pressure, in rare cases increased diastolic blood pressure (lower blood pressure value),
- Abdominal pain (including pain in the upper and lower abdomen, discomfort / bloating),
- Nausea, vomiting or diarrhoea,
- Acne
- Hair loss (alopecia),
- Skin rash (including spot-like rash),
- Itching (sometimes over the entire body)
- Irregular menstrual bleeding including heavy bleeding (menorrhagia), minor bleeding (hypomenorrhoea), irregular bleeding (oligomenorrhoea) and absence of bleeding (amenorrhoea),
- Spotting (vaginal hemorrhage and metrorrhagia)
- Painful menstruation (dysmenorrhoea), pelvic pain,
- Breast enlargement including breast swelling, breast oedema,
- Vaginal discharge,
- Ovarian cysts,
- pelvic pain,
- Fatigue including weakness, fatigue and general malaise,
- Weight change (increase, decrease or fluctuation)

**Rare** (between 1 and 10 in every 10,000 users may be affected):

- Inflammation in the fallopian tubes or ovaries
- Inflammation of the cervix (cervicitis)
- Urinary tract infection, bladder infection (cystitis)
- Breast infection (mastitis)
- Fungal infections (such as Candida), viral infections, cold sores
- Flu (influenza), bronchitis, upper respiratory infections, sinus infection (sinusitis)
- Asthma
- Increase in respiratory rate (hyperventilation)
- Benign growths in the uterus (fibroids)
- Benign growths in the fatty tissue of the breast (breast lipomas)
- Anaemia
- hypersensitivity (allergic reactions),
- development of male characteristics (virilism),

DIENOGEST 2 MG + ETHINYLESTRADIOL 0.03 MG FILM-COATED TABLET

- severe loss of appetite (anorexia),
- depression,
- mental disorders
- insomnia
- sleep disorders,
- aggression,
- ischemic stroke (decreased or interrupted blood supply to the brain),
- vascular brain disorder (disorder of blood flow to the brain)
- change of muscle tension - dystonia (persistent muscle contractions causing twisting or atypical posture),
- dry or irritated eyes,
- oscillopsia (eye disorder when objects seen appear to move) or other vision disorders
- sudden hearing loss,
- tinnitus,
- vertigo,
- hearing impairment,
- cardiovascular disorders (disorders of blood supply to the heart),
- fast heart rhythm (tachycardia)
- harmful blood clots in a vein or artery for example:
  - o in a leg or foot (i.e. deep vein thrombosis)
  - o in a lung (i.e. pulmonary embolism)
  - o heart attack
  - o stroke
  - o mini-stroke or temporary stroke-like symptoms, known as a transient ischaemic attack (TIA)
  - o blood clots in the liver, stomach/intestine, kidneys or eye.
- increased diastolic blood pressure (the lowest blood pressure value achieved between two heart beats),
- orthostatic hypotension (dizziness or fainting when standing up from sitting or lying down),
- hot flushes,
- varicose veins,
- venous disorders, vein pain
- asthma,
- deep breathing,
- gastritis,
- inflammation of the intestines,
- indigestion (dyspepsia)
- skin reactions
- skin disorders including allergic skin reaction, neurodermatitis/atopic dermatitis, eczema, psoriasis,
- excessive sweating,
- chloasma (golden-brown pigment spots, so-called “pregnancy spots”, especially on the face),
- pigment disorders/increased pigmentation,
- seborrhea (oily skin),
- dandruff,
- hirsutism (masculine hair growth),
- orange skin,
- spider naevi (netted blood vessels with a central red spot on the skin),
- back pain,

- discomfort of bones and muscles,
- muscle pain,
- pain in arms and legs,
- abnormal growth of cells on the surface of the cervix (cervical dysplasia),
- Pain or cysts on the uterine appendages (fallopian tubes and ovaries),
- breast cysts,
- fibrocystic breast disease (benign growths in the breast),
- pain during intercourse (dyspareunia),
- mammary gland secretion (galactorrhoea),
- menstrual disorders,
- chest pain,
- peripheral oedema (fluid retention in the body),
- flu-like disease,
- inflammation,

The adverse reactions that have been reported with the use of pills and for which we do not know the exact frequency are: mood swings, increased or decreased sexual desire (libido), contact lens intolerance, urticaria, skin disorders such as erythema nodosum or multiforme, breast discharge, fluid retention.

The chance of having a blood clot may be higher if you have any other conditions that increase this risk (See section 2 for more information on the conditions that increase risk for blood clots and the symptoms of a blood clot)

#### **Description of selected adverse reactions**

Adverse reactions with very low incidence or delayed onset of symptoms related to the group of combined oral contraceptives are listed below (see also “Do not take Raener 2mg/0.03 mg” and “What you need to know before you take Raener 2mg/0.03 mg”).

#### *Tumors*

- The frequency of breast cancer diagnosis among users of the “pill” is slightly increased. Because breast cancer rarely appears in women under 40, the risk of developing breast cancer is minimal in comparison with the overall risk. It is not known whether there is a causal relationship to the use of combined oral contraceptives.
- Liver tumors (benign and malignant)

#### *Other conditions*

- women with hypertriglycerolemia (increased amounts of fat in the blood may result in an increased risk of inflammation of the pancreas during combination oral contraceptives)
- increased blood pressure
- occurrence or worsening of conditions where the association with combined oral contraceptives is unclear: jaundice and / or itching associated with cholestasis (interrupted outflow of bile), gallstones, porphyria (metabolic disorder), systemic lupus erythematosus (chronic autoimmune disease), haemolytic uremic syndrome (a disease caused by the formation of blood clots), a nerve disease called Sydenham's chorea, gestational herpes (a blistering disease occurring during pregnancy), hearing loss caused by otosclerosis
- hepatic impairment

- changes in glucose tolerance or peripheral insulin resistance
- Crohn's disease, ulcerative colitis
- chloasma (brownish yellow spots on the skin)

#### *Interactions*

Unexpected bleeding and/or contraceptive failure may be due to interactions of other medicines with oral contraceptives (e. g. St. John's wort, medicines to treat epilepsy, tuberculosis, HIV infection and other infections). See also "Other medicines and Jeanine".

#### **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 HPRÁ Pharmacovigilance Website: [www.hpra.ie](http://www.hpra.ie) By reporting side effects you can help provide more information on the safety of this medicine.

#### **More about the birth control pill**

The combined pill can also produce non-contraceptive health benefits.

Your menstrual bleeding may be weaker and shorter. This may result in a lower risk of anemia. The pain associated with menstruation may be less or completely disappear.

In addition, users of pills containing 50 micrograms of ethinylestradiol (high-dose pill) have been reported to have a lower incidence of some serious diseases. These include benign breast diseases, ovarian cysts, pelvic infections (inflammatory diseases of small pelvis organs), ectopic pregnancy (the fetus develops outside the uterus), and endometrial cancer (uterine mucosa) and ovaries. This may also apply to the use of a low-dose pill, but has so far been confirmed only for endometrial and ovarian cancer

#### **5. How to store Raener 2mg/0.03 mg**

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

Do not use this medicine after the expiry date which is stated on the box and blister pack, after "EXP". The expiry date refers to the last day of that month.

Do not store above 30°C

Keep the blister in the outer carton in order to protect from the light.

Do not throw away any medicines 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 Raener 2mg/0.03 mg contains**

- The active substances are dienogest and ethinylestradiol. One coated tablet contains 2.0 mg of dienogest and 0.03 mg of ethinylestradiol.
- The other ingredients are:

*Tablet core:* lactose monohydrate, magnesium stearate, maize starch, povidone.

*Film-coating:* aquarius coating system containing: hypromellose 2910, macrogol 400 (PEG), titanium dioxide.

**What Raener 2mg/0.03 mg looks like and contents of the pack**

Raener 2mg/0.03 mg is a white, round, biconvex film-coated tablet.

Raener 2mg/0.03 mg is available in packages containing 21, 3x21 and 6x21 film-coated tablets.

Not all pack sizes may be marketed.

**Marketing Authorisation Holder and Manufacturer**

Laboratorios León Farma SA

La Vallina s/n,

Polígono Industrial Navatejera,

24193 Villaquilambre León Spain

**This leaflet was last revised in 10/2024**