

## **Package leaflet: Information for the user**

### **Ethinylestradiol / Drospirenone Leon Farma & Placebo 0.03 mg/3 mg0.03 mg/3 mg 28 film-coated tablets**

**(ethinylestradiol/drospirenone)**

**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, tell your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

#### **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”)

#### **What is in this leaflet:**

1. What Ethinylestradiol / Drospirenone Leon Farma & Placebo 0.03 mg/3 mg is and what it is used for
2. What you need to know before you take Ethinylestradiol / Drospirenone Leon Farma & Placebo 0.03 mg/3 mg
3. How to take Ethinylestradiol / Drospirenone Leon Farma & Placebo 0.03 mg/3 mg
4. Possible side effects
5. How to store Ethinylestradiol / Drospirenone Leon Farma & Placebo 0.03 mg/3 mg
6. Contents of the pack and other information

**1. What Ethinylestradiol / Drospirenone Leon Farma & Placebo 0.03 mg/3 mg is and what it is used for**

Ethinylestradiol / Drospirenone Leon Farma & Placebo 0.03 mg/3 mg is a contraceptive pill and is used to prevent pregnancy.

Each of the 21 yellow tablets contains a small amount of two different female hormones, namely drospirenone and ethinylestradiol.

The 7 white tablets contain no active substances and are also called placebo tablets.

Contraceptive pills that contain two hormones are called “combination” pills.

**2. What you need to know before you take Ethinylestradiol / Drospirenone Leon Farma & Placebo 0.03 mg/3 mg**

**General notes**

Before you start using Ethinylestradiol / Drospirenone Leon Farma & Placebo 0.03 mg/3 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 Ethinylestradiol / Drospirenone Leon Farma & Placebo 0.03 mg/3 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 Ethinylestradiol / Drospirenone Leon Farma & Placebo 0.03 mg/3 mg, or where the reliability of Ethinylestradiol / Drospirenone Leon Farma & Placebo 0.03 mg/3 mg may be decreased. In such situations you should either not have sex or you should take extra non-hormonal contraceptive precautions, e.g., use a condom or another barrier method. Do not use rhythm or temperature methods. These methods can be unreliable because Ethinylestradiol / Drospirenone Leon Farma & Placebo 0.03 mg/3 mg alters the monthly changes of the body temperature and of the cervical mucus.

**Ethinylestradiol / Drospirenone Leon Farma & Placebo 0.03 mg/3 mg, like other hormonal contraceptives, does not protect against HIV infection (AIDS) or any other sexually transmitted disease.**

**Do not take Ethinylestradiol / Drospirenone Leon Farma & Placebo 0.03 mg/3 mg:**

You should not use Ethinylestradiol / Drospirenone Leon Farma & Placebo 0.03 mg/3 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 have (or have ever had) a blood clot in a blood vessel or 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 or have ever had a heart attack or 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 the risk of a blood clot in the arteries. This applies to the following diseases:
  - severe diabetes with blood vessels 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 have (or have ever had) a liver disease and your liver function is still not normal.
- if your kidneys are not working well (renal failure)
- if you have (or have ever had) a tumour in the liver
- if you have (or have ever had) or if you are suspected of having breast cancer or cancer of the genital organs
- if you have any unexplained bleeding from the vagina
- if you are allergic to ethinylestradiol or drospirenone, or any of the other ingredients of this medicine (listed in section 6). This may cause itching, rash or swelling.
- if you have hepatitis C and are taking the medicinal products containing ombitasvir/paritaprevir/ritonavir and dasabuvir (see also in section Other medicines and Ethinylestradiol / Drospirenone Leon Farma & Placebo 0.03 mg/3 mg).

### **Warnings and precautions**

Talk to your doctor or pharmacist before taking Ethinylestradiol / Drospirenone Leon Farma & Placebo 0.03 mg/3 mg.

### **When to take special care with Ethinylestradiol / Drospirenone Leon Farma & Placebo 0.03 mg/3 mg**

When should you contact your doctor?

#### Seek urgent medical attention

- 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”.

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

If the condition develops, or gets worse while you are using Ethinylestradiol / Drospirenone Leon Farma & Placebo 0.03 mg/3 mg, you should also tell your doctor. In some situations you need to take special care while using Ethinylestradiol / Drospirenone Leon Farma & Placebo 0.03 mg/3 mg or any other combination pill and your doctor may need to examine you regularly.

- if a close relative has or has ever had breast cancer
- if you have a disease of the liver or the gallbladder

- if you have diabetes
- if you have depression. Some women using hormonal contraceptives including <product name> 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.
- 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 defence system);
- if you have haemolytic uraemic syndrome (HUS - a disorder of blood clotting 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 Ethinylestradiol / Drospirenone Leon Farma & Placebo 0.03 mg/3 mg;
- If you have an inflammation in the veins under the skin (superficial thrombophlebitis);
- If you have varicose veins.
- if you have epilepsy (see "Ethinylestradiol / Drospirenone Leon Farma & Placebo 0.03 mg/3 mg and using other medicines")
- if you have a disease that first appeared during pregnancy or earlier use of sex hormones (for example, hearing loss, a blood disease called porphyria, skin rash with blisters during pregnancy (gestational herpes), a disease of the nerves in which sudden movements of the body occur (Sydenham's chorea)).
- if you have or have ever had chloasma (a discolouration of the skin, especially of the face or neck known as "pregnancy patches". If so, avoid direct sunlight or ultraviolet light.
- if you have hereditary angioedema, products containing estrogens may cause or worsen the symptoms. You should see your doctor immediately if you experience symptoms of angioedema such as swollen face, tongue and/or throat and/or difficulty swallowing or hives together with difficulty breathing.

## BLOOD CLOTS

Using a combined hormonal contraceptive such as Ethinylestradiol / Drospirenone Leon Farma & Placebo 0.03 mg/3 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 Ethinylestradiol / Drospirenone Leon Farma & Placebo 0.03 mg/3 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: <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> </li> </ul>	Deep vein thrombosis
<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>	Pulmonary embolism
<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>	Retinal vein thrombosis (blood clot in the eye)
<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>	Heart attack

Are you experiencing any of these signs?	What are you possibly suffering from?
<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> <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>	Stroke
<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>	Blood clots blocking other blood vessels

## 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 thrombosis). 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 for the first time. 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 Ethinylestradiol / Drospirenone Leon Farma & Placebo 0.03 mg/3 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 Ethinylestradiol / Drospirenone Leon Farma & Placebo 0.03 mg/3 mg is small.

- 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.
- 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.
- Out of 10,000 women who are using a combined hormonal contraceptive that contains drospirenone, such as Ethinylestradiol / Drospirenone Leon Farma & Placebo 0.03 mg/3 mg, between about 9 and 12 women will develop a blood clot in a year.
- 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 Ethinylestradiol / Drospirenone Leon Farma & Placebo 0.03 mg/3 mg	About 9-12 out of 10,000 women

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

The risk of a blood clot with Ethinylestradiol / Drospirenone Leon Farma & Placebo 0.03 mg/3 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 Ethinylestradiol / Drospirenone Leon Farma & Placebo 0.03 mg/3 mg may need to be stopped several weeks before surgery or while you are less mobile. If you need to stop Ethinylestradiol / Drospirenone Leon Farma & Placebo 0.03 mg/3 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 Ethinylestradiol / Drospirenone Leon Farma & Placebo 0.03 mg/3 mg needs to be stopped.

If any of the above conditions change while you are using Ethinylestradiol / Drospirenone Leon Farma & Placebo 0.03 mg/3 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 Ethinylestradiol / Drospirenone Leon Farma & Placebo 0.03 mg/3 mg is very small but can increase:

- with increasing age (beyond about 35 years);
- **if you smoke.** When using a combined hormonal contraceptive like Ethinylestradiol / Drospirenone Leon Farma & Placebo 0.03 mg/3 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 (less than about 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 Ethinylestradiol / Drospirenone Leon Farma & Placebo 0.03 mg/3 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.

### **Ethinylestradiol / Drospirenone Leon Farma & Placebo 0.03 mg/3 mg 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. For example it may be that more tumours are detected

in women on combination pills because they are examined by their doctor more often. The occurrence of breast tumours becomes gradually less after stopping the combination hormonal contraceptives. 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. Contact your doctor if you have unusually severe abdominal pain.

### **Bleeding between periods**

During the first few months that you are taking Ethinylestradiol / Drospirenone Leon Farma & Placebo 0.03 mg/3 mg, you may have unexpected bleeding (bleeding outside the week when you are taking the white tablets). If this bleeding occurs for more than a few months, or if it begins after some months, your doctor must find out what is wrong.

### **What to do if no bleeding occurs during the placebo days**

If you have taken all the yellow active tablets correctly, have not had vomiting or severe diarrhoea and you have not taken any other medicines, it is highly unlikely that you are pregnant.

If the expected bleeding does not happen twice in succession, you may be pregnant. Contact your doctor immediately. Do not start the next strip until you are sure that you are not pregnant.

### **Other medicines and Ethinylestradiol / Drospirenone Leon Farma & Placebo 0.03 mg/3 mg**

Tell your doctor which medicines or herbal products you are taking, have recently taken or might take. Also tell any other doctor or dentist who prescribes another medicine (or the pharmacist) that you use Ethinylestradiol / Drospirenone Leon Farma & Placebo 0.03 mg/3 mg. They can tell you if you need to take additional contraceptive precautions (for example condoms) and, if so, for how long.

Do not use Ethinylestradiol / Drospirenone Leon Farma & Placebo 0.03 mg/3 mg if you have Hepatitis C and are taking the medicinal products containing ombitasvir/paritaprevir/ritonavir and dasabuvir as 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.

Ethinylestradiol / Drospirenone Leon Farma & Placebo 0.03 mg/3 mg can be restarted approximately 2 weeks after completion of this treatment. See section “Do not take Ethinylestradiol / Drospirenone Leon Farma & Placebo 0.03 mg/3 mg”.

Some medicines can have an influence on the blood levels of Ethinylestradiol / Drospirenone Leon Farma & Placebo 0.03 mg/3 mg and can make it less effective in preventing pregnancy, or can cause unexpected bleeding. These include:

- medicines used for the treatment of
  - epilepsy (e.g. primidone, phenytoin, barbiturates, carbamazepine, oxcarbazepine)
  - 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) or other infections (griseofulvin)
  - high blood pressure in the blood vessels in the lungs (bosentan)
- the herbal remedy St John's wort.

Ethinylestradiol / Drospirenone Leon Farma & Placebo 0.03 mg/3 mg may influence the effect of other medicines, e.g.

- medicines containing ciclosporin
- the anti-epileptic lamotrigine (this could lead to an increased frequency of seizures)

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

### **Laboratory tests**

If you need a blood test, tell your doctor or the laboratory staff that you are taking the pill, because hormone contraceptives can affect the results of some tests.

### **Pregnancy and breast-feeding**

#### **Pregnancy**

If you are pregnant, do not take Ethinylestradiol / Drospirenone Leon Farma & Placebo 0.03 mg/3 mg. If you become pregnant while taking Ethinylestradiol / Drospirenone Leon Farma & Placebo 0.03 mg/3 mg stop immediately and contact your doctor. If you want to become pregnant, you can stop taking Ethinylestradiol / Drospirenone Leon Farma & Placebo 0.03 mg/3 mg at any time (see also “If you want stop taking Ethinylestradiol / Drospirenone Leon Farma & Placebo 0.03 mg/3 mg”).

#### **Breast-feeding**

Use of Ethinylestradiol / Drospirenone Leon Farma & Placebo 0.03 mg/3 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.

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

### **Driving and using machines**

There is no information suggesting that use of Ethinylestradiol / Drospirenone Leon Farma & Placebo 0.03 mg/3 mg affects driving or use of machines.

Ethinylestradiol / Drospirenone Leon Farma & Placebo 0.03 mg/3 mg contains lactose.

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

### **3. How to take Ethinylestradiol / Drospirenone Leon Farma & Placebo 0.03 mg/3 mg**

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

Each blister contains 21 active yellow tablets and 7 white placebo tablets.

The two differently coloured tablets of Ethinylestradiol / Drospirenone Leon Farma & Placebo 0.03 mg/3 mg are arranged in order. A strip contains 28 tablets.

Take one tablet of Ethinylestradiol / Drospirenone Leon Farma & Placebo 0.03 mg/3 mg every day, if necessary with a small amount of water. You may take the tablets with or without food, but you should take the tablets every day around the same time.

**Do not confuse the tablets:** take a yellow tablet once per day for the first 21 days, and then one white tablet per day for the last 7 days. Then you should start a new strip (21 yellow tablets and 7 white tablets). So there is no gap between two strips.

Due to the different composition of the tablets, it is necessary to begin with the first tablet on the upper left and that you take the tablets every day. For the correct order, follow the direction of the arrows on the strip.

### **Preparation of the strip**

To help you remember to take the contraceptive, every strip (blister) of <Drosp/EE> tablets comes with seven adhesive stickers which have the days of the week printed on them. You must know the day of the week you are going to start taking the tablets.

According to the day of the week you are going to start taking the tablets, you should choose the corresponding adhesive week sticker. For example, if you begin on Wednesday, use the sticker which says "WED". Then stick the corresponding sticker in the upper left hand corner of the strip, on the "Start" position. Now you have a day of the week above every tablet and you can see if you have taken a tablet. The arrows show the order you should take the tablets in.

During the 7 days when you are taking the white placebo tablets (the placebo days), bleeding should begin (so-called withdrawal bleeding). This usually starts on the 2<sup>nd</sup> or 3<sup>rd</sup> day after the last yellow active tablet of Ethinylestradiol / Drospirenone Leon Farma & Placebo 0.03 mg/3 mg. Once you have taken the last white tablet, you should start with the following strip, whether your bleeding has stopped or not. This means that you should start every strip on the same day of the week, and that the withdrawal bleed should occur on the same days each month.

If you use Ethinylestradiol / Drospirenone Leon Farma & Placebo 0.03 mg/3 mg in this manner, you are protected against pregnancy also during the 7 days when you are taking a placebo tablet.

### **When can you start with the first strip**

- *If you have not used a contraceptive with hormones in the previous month*  
Begin with Ethinylestradiol / Drospirenone Leon Farma & Placebo 0.03 mg/3 mg on the first day of your usual cycle (that is, the first day of your period). If you start Ethinylestradiol / Drospirenone Leon Farma & Placebo 0.03 mg/3 mg on the first day of your period you are immediately protected against pregnancy. You may also begin on day 2-5 of the cycle, but then you must use extra protective measures (for example, a condom) for the first 7 days.
- *Changing from a combination hormonal contraceptive, or combination contraceptive vaginal ring or patch*  
You should start taking Ethinylestradiol / Drospirenone Leon Farma & Placebo 0.03 mg/3 mg preferably on the day after the last active tablet (the last tablet containing active substances) of your previous pill, but at the latest on the day after the tablet-free days of your previous pill

(or after the last inactive tablet of your previous pill). When changing from a combination contraceptive vaginal ring or patch, follow the advice of your doctor.

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

You may switch any day from the progestogen-only pill however, (from an implant or an IUD you should switch on the day of its removal, from an injectable when the next injection would be due) but in all of these cases use extra protective measures (for example, a condom) for the first 7 days of tablet-taking.

- *After a miscarriage or termination of your pregnancy*

Follow the advice of your doctor.

- *After having a baby*

You can start Ethinylestradiol / Drospirenone Leon Farma & Placebo 0.03 mg/3 mg between 21 and 28 days after having a baby. If you start later than day 28, use a so-called barrier method of contraception (for example, a condom) during the first seven days of Ethinylestradiol / Drospirenone Leon Farma & Placebo 0.03 mg/3 mg use.

If, after having a baby, you have had sex before starting Ethinylestradiol / Drospirenone Leon Farma & Placebo 0.03 mg/3 mg, be sure that you are not pregnant or wait until your next period.

- *If you are breastfeeding and want to start Ethinylestradiol / Drospirenone Leon Farma & Placebo 0.03 mg/3 mg (again) after having a baby*

Read the section on "Breast-feeding".

Ask your doctor what to do if you are not sure when to start.

### **If you take more Ethinylestradiol / Drospirenone Leon Farma & Placebo 0.03 mg/3 mg than you should**

There are no reports of serious harmful results of taking too many Ethinylestradiol / Drospirenone Leon Farma & Placebo 0.03 mg/3 mg tablets.

If you take several tablets at once then you may have signs of overdose such as of nausea or vomiting. Young girls may have bleeding from the vagina.

If you have taken too many Ethinylestradiol / Drospirenone Leon Farma & Placebo 0.03 mg/3 mg tablets, or you discover that a child has taken some, ask your doctor or pharmacist for advice.

### **If you forget to take Ethinylestradiol / Drospirenone Leon Farma & Placebo 0.03 mg/3 mg**

The tablets in the 4<sup>th</sup> row of the strip are the placebo tablets. If you forget one of these tablets, this has no effect on the reliability of <inventd name> . Throw away the forgotten placebo tablet .

If you miss a yellow, active tablet from the 1<sup>st</sup>, 2<sup>nd</sup> or 3<sup>rd</sup> row, do as follows:

- If you are **less than 12 hours** late taking a tablet, the protection against pregnancy is not reduced. Take the tablet as soon as you remember and then take the following tablets again at the usual time.

- If you are **more than 12 hours** late taking a tablet, the protection against pregnancy may be reduced. The greater the number of tablets that you have forgotten, the greater is the risk of becoming pregnant.

The risk of incomplete protection against pregnancy is greatest if you forget a yellow tablet at the beginning or at the end of the strip. Therefore, you should keep to the following rules (see the diagram below):

- **More than one tablet forgotten in this strip**

Contact your doctor.

- **One tablet forgotten in week 1**

Take the forgotten tablet as soon as you remember, even if that means that you have to take two tablets at the same time. Continue taking the tablets at the usual time and use **extra precautions** for the next 7 days, for example, a condom. If you have had sex in the week before forgetting the tablet you should contact your doctor as there is a chance you may have become pregnant

- **One tablet forgotten in week 2**

Take the forgotten tablet as soon as you remember, even if that means that you have to take two tablets at the same time. Continue taking the tablets at the usual time. The protection against pregnancy is not reduced, and you do not need to take extra precautions.

- **One tablet forgotten in week 3**

You can choose between two possibilities:

1. Take the forgotten tablet as soon as you remember, even if that means that you have to take two tablets at the same time. Continue taking the tablets at the usual time. Instead of taking the white placebo tablets on this strip, throw them away, and start the next strip.

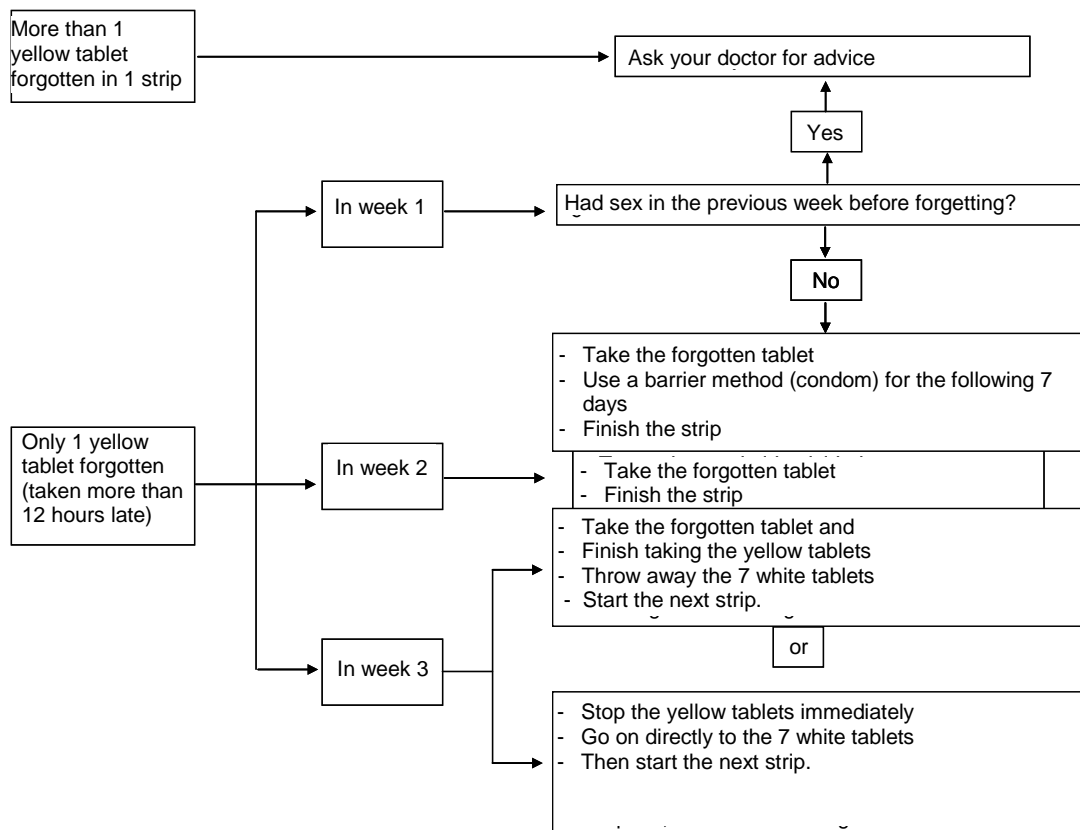
Most likely, you will have a period at the end of the second strip - while taking the white placebo tablets - but you may have light or menstruation-like bleeding during the second strip.

2. You can also stop the active yellow tablets and go directly to the 7 white placebo tablets (**before taking the placebo tablets, record the day on which you forgot your tablet**). If you want to start a new strip on the day you always start, take the placebo tablets for *less than 7 days*.

If you follow one of these two recommendations, you will remain protected against pregnancy.

- If you have forgotten any of the tablets in a strip, and you do not have a bleeding during the normal placebo days, you may be pregnant. Contact your doctor before you start the next strip.

The following diagram describes how to proceed if you forget to take your tablet(s):



### **What to do in the case of vomiting or severe diarrhoea**

If you vomit within 3-4 hours after taking an active yellow tablet or you have severe diarrhoea, there is a risk that the active substances in the pill will not be fully taken up by your body. The situation is almost the same as forgetting a tablet. After vomiting or diarrhoea, take another yellow tablet from a reserve strip as soon as possible. If possible take it *within 12 hours* of when you normally take your pill. If that is not possible or 12 hours have passed, you should follow the advice given under "If you forget to take Ethinylestradiol / Drospirenone Leon Farma & Placebo 0.03 mg/3 mg".

### **Delaying your period: what you need to know**

Even though it is not recommended, you can delay your period by not taking the white placebo tablets from the 4<sup>th</sup> row and going straight to a new strip of Ethinylestradiol / Drospirenone Leon Farma & Placebo 0.03 mg/3 mg and finishing it. You may experience light or menstruation-like bleeding while using this second strip. Finish this second strip by taking the 7 white tablets from the 4<sup>th</sup> row. Then start your next strip.

*You should ask your doctor for advice before deciding to delay your menstrual period.*

### **Changing the first day of your period: what you need to know**

If you take the tablets according to the instructions, then your period will begin during the placebo week. If you have to change this day, reduce the number of placebo days – when you take the white placebo tablets - (*but never increase them – 7 is the maximum!*). For example, if you normally start taking the placebo tablets on a Friday, and you want to change this to a Tuesday (3 days earlier) start a new strip 3 days earlier than usual. If you make the placebo interval very short (for example, 3 days or less), you may not have any bleeding during these days. You may then experience light or menstruation-like bleeding.

*If you are not sure what to do, consult your doctor.*

### **If you want stop taking Ethinylestradiol / Drospirenone Leon Farma & Placebo 0.03 mg/3 mg**

You can stop taking Ethinylestradiol / Drospirenone Leon Farma & Placebo 0.03 mg/3 mg whenever you want. If you do not want to become pregnant, ask your doctor for advice about other reliable methods of birth control. If you want to become pregnant, stop taking Ethinylestradiol / Drospirenone Leon Farma & Placebo 0.03 mg/3 mg and wait for a period before trying to become pregnant. You will be able to calculate the expected delivery date more easily.

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

## **4. Possible side effects**

Like all medicines, Ethinylestradiol / Drospirenone Leon Farma & Placebo 0.03 mg/3 mg can cause side effects, although not everybody gets them. If you get any side effect, particularly if severe and persistent, or have any change to your health that you think may be due to Ethinylestradiol / Drospirenone Leon Farma & Placebo 0.03 mg/3 mg, please talk to 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 on the different risks from taking combined hormonal contraceptives please see section 2 “What you need to know before you take Ethinylestradiol / Drospirenone Leon Farma & Placebo 0.03 mg/3 mg”.

The following is a list of the side effects that have been linked with the use of Ethinylestradiol / Drospirenone Leon Farma & Placebo 0.03 mg/3 mg.

**Common side effects** (may affect up to 1 in 10 people):

- menstrual disorders, bleeding between periods, breast pain, breast tenderness
- headache, depressive mood
- migraine
- nausea
- thick, whitish vaginal discharge and vaginal yeast infection.

**Uncommon side effects** (may affect up to 1 in 100 people):

- changes in interest in sex, breast enlargement
- high blood pressure, low blood pressure
- vomiting, diarrhoea
- acne, skin rash, severe itching, hair loss (alopecia)
- infection of the vagina
- fluid retention and body weight changes.

**Rare side effects** (may affect up to 1 in 1000 people):

- allergic reactions (hypersensitivity), asthma
- breast secretion
- hearing impairment
- the skin conditions, erythema nodosum (characterized by painful reddish skin nodules) or erythema multiforme (characterized by rash with target-shaped reddening or sores).
- harmful blood clots in a vein or artery for example:
  - in a leg or foot (i.e. DVT)
  - in a lung (i.e. PE)
  - heart attack
  - stroke
  - mini-stroke or temporary stroke-like symptoms, known as a transient ischaemic attack (TIA)
  - blood clots in the liver, stomach/intestine, kidneys or eye.

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)

**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 Ethinylestradiol / Drospirenone Leon Farma & Placebo 0.03 mg/3 mg**

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

This medicinal product does not require any special storage conditions.

Do not use

this medicine after the expiry date which is stated on the blister/carton after "EXP:" The expiry date refers to the last day of that month.

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 Ethinylestradiol / Drospirenone Leon Farma & Placebo 0.03 mg/3 mg contains:**

A strip of **Ethinylestradiol / Drospirenone Leon Farma & Placebo 0.03 mg/3 mg** contains 21 yellow active tablets in the 1<sup>st</sup>, 2<sup>nd</sup> and 3<sup>rd</sup> rows of the strip and 7 white placebo tablets in row 4.

#### **Active tablets**

The active substances are ethinylestradiol 0.03 mg and drospirenone 3 mg.

The other ingredients are:

Tablet core: lactose monohydrate, maize starch, pregelatinised starch (maize), croscopovidone, povidone, polysorbate 80, magnesium stearate.

Coating: Polyvinyl alcohol partial hydrolyzed, titanium dioxide (E171), macrogol 3350, talc, yellow iron oxide (E172).

#### **Placebo tablets**

Tablet core: lactose anhydrous, povidone, magnesium stearate.

Coating: Polyvinyl alcohol partial hydrolyzed, titanium dioxide (E171), macrogol 3350, talc.

### **What Ethinylestradiol / Drospirenone Leon Farma & Placebo 0.03 mg/3 mg looks like and contents of the package**

Active tablets are yellow, round film-coated tablets.

Placebo tablets are white, round film-coated tablets.

Ethinylestradiol / Drospirenone Leon Farma & Placebo 0.03 mg/3 mg is available in boxes of 1, 2, 3, 6 and 13 blisters, each one containing 28 tablets (21 active plus 7 placebo tablets)

Not all pack sizes may be marketed.

## **Marketing Authorisation Holder and Manufacturer**

### **Marketing Authorisation Holder**

[To be completed nationally]

**Manufacturer**

Laboratorios León Farma, S.A.  
Pol. Ind. Navatejera.  
C/ La Vallina s/n  
24008 - Villaquilambre, León.  
Spain

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

<b>Norway</b>	Drosetil 28
<b>Austria</b>	Naraya
<b>Bulgary</b>	Drosetil
<b>Denmark</b>	Drospira
<b>Estonia</b>	LluviEight
<b>Greece</b>	Drospirenone+Ethinylestradiol /Intermed (3+0.03)mg/tab επικαλυμμένο με λεπτό υμένιο δισκίο
<b>Spain</b>	Etinilestradiol/drospirenona diario cinfalab 0,03 mg/3 mg comprimidos recubiertos con película EF
<b>Hungary</b>	ALTFORALLE 3 mg / 0,03 mg Filmtabletta
<b>Ireland</b>	Ethinylestradiol/Drospirenone Leon Farma & placebo
<b>Portugal</b>	Drosure
<b>Romania</b>	Drosetil
<b>Slovak Republic</b>	ALTFORALLE

This leaflet was last approved in: