

PACKAGE LEAFLET: INFORMATION FOR THE USER

<invented name> 0.10 mg/0.02 mg film-coated tablet

Levonorgestrel / Ethinylestradiol

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

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or your pharmacist or nurse.
- 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 or nurse. This includes any possible side effects not listed in this leaflet.

In this leaflet:

1. What <invented name> is and what it is used for
2. What you need to know before you take <invented name>
 - When you should not use <invented name>
 - When to take special care with <invented name>
 - <invented name> and venous and arterial blood clots
 - <invented name> and cancer
 - Bleeding between periods
 - What to do if no bleeding occurs during the gap week
 - Other medicines and <invented name>
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 - Important information about some of the ingredients of <invented name>
3. How to take <invented name>
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 - What to do in the case of vomiting or severe diarrhoea
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1. What <INVENTED NAME> is and what it is used for

- <invented name> is a contraceptive pill used to prevent pregnancy.
- Each tablet contains a small amount of two different female hormones, namely levonorgestrel and ethinylestradiol.
- Contraceptive pills that contain two hormones are called ‘combination pills.’

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

General notes

Before you can begin taking <invented name>, 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 <invented name>, or where the reliability of <invented name> 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 <invented name> alters the monthly changes of body temperature and of the cervical mucus.

<invented name>, like other hormonal contraceptives, does not protect against HIV infection (AIDS) or any other sexually transmitted disease.

While you are receiving this medication you should see your doctor regularly, at least twice a year.

If you have any unusual symptoms such as unexplained pains in the chest, abdomen or legs you must consult your doctor immediately.

When you should not use <invented name>

Do not use <invented name>:

- if you have (or have ever had) a blood clot in a blood vessel of the leg (thrombosis), lung (pulmonary embolism) or other organs
- if you have (or have ever had) a heart attack or stroke
- if you have (or have ever had) a disease that can be an indicator of a heart attack in the future (for example, angina pectoris, which causes severe pain in the chest) or of a stroke (for example, a passing slight stroke with no residual effects)
- if you have a disease that may increase the risk of a clot in the arteries. This applies to the following diseases:
 - diabetes with damaged blood vessels
 - very high blood pressure
 - a very high level of fat in the blood (cholesterol or triglycerides)
- if you have a disturbance of blood clotting (for example, protein C deficiency)
- if you have (or have ever had) a certain form of migraine (with so-called focal neurological symptoms)
- if you have (or have ever had) an inflammation of the pancreas (pancreatitis)
- 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 levonorgestrel or ethinylestradiol, or any of the other ingredients of this medicine (listed in section 6). This can be recognized by itching, rash or swelling.

When to take special care with <invented name>

In some situations you need to take special care while using <invented name> or any other combination pill, and your doctor may need to examine you regularly. If any of the following conditions applies to you, tell your doctor before starting to use <invented name>. Also, if any of the following applies or if any of the conditions develops or worsens while you are using <invented name> consult your doctor:

- 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
- if you have Crohn's disease or inflammatory bowel disease (ulcerative colitis)
- if you have a blood disease called HUS (haemolytic uraemic syndrome) which causes kidney damage
- if you have a blood disease called sickle cell anaemia
- if you have epilepsy (see page “<invented name> and using other medicines”)
- if you have a disease of the immune system called SLE (systemic lupus erythematosus)
- 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 nerve disease causing sudden movements of the body (Sydenham's chorea))
- if you have or have ever had chloasma (a discoloration 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 oestrogens may cause or worsen 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.

<invented name> and venous and arterial blood clots

The use of any combination pill, including <invented name>, increases a woman's risk of developing a **venous blood clot (venous thrombosis)** compared with women who do not take any contraceptive pill.

The risk of venous blood clots in users of combination pills increases:

- with increasing age
- if you are overweight
- if one of your close relatives ever had a blood clot in the leg, lung (pulmonary embolism), or other organ at a young age
- if you have to 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 that you are using <invented name> as you may have to stop taking it. Your doctor will tell you when to start again. This is usually about two weeks after you are back on your feet.

Your chances of having a blood clot are increased by taking the Pill.

- Of 100,000 women who are not on the Pill and not pregnant, about 5-10 may have a blood clot in a year.

- Of 100,000 women taking a Pill like <invented name>, 30-40 may have a blood clot in a year, the exact number is unknown.
- Of 100,000 women who are pregnant, around 60 may have a blood clot in a year.

A blood clot in the veins may travel to the lungs and may block blood vessels (called a lung embolus). Formation of blood clots in the veins may be fatal in 1-2% of cases.

The level of risk may vary according to the type of pill you take. Discuss with your doctor the available options.

The use of combination pills has been connected with an increase of the risk of an **arterial blood clot (arterial thrombosis)**, for example, in the blood vessels of the heart (heart attack) or the brain (stroke).

The risk of an arterial blood clot in users of combination pills increases:

- with increasing age
- **if you smoke. You are strongly advised to stop smoking when you use <invented name>, especially if you are older than 35 ye ars.**
- if the fat content of your blood is increased (cholesterol or triglycerides)
- if you have high blood pressure
- if you suffer from migraine
- if you have a problem with your heart (valve disorder, a disturbance of the cardiac rhythm)

Stop taking <invented name> and contact your doctor immediately if you notice possible signs of a blood clot, such as:

- severe pain and/or swelling in one of your legs
- sudden severe pain in the chest which may reach the left arm
- sudden breathlessness
- sudden cough without an obvious cause
- any unusual, severe or long-lasting headache or worsening of migraine
- partial or complete blindness or double vision
- difficulty in speaking or inability to speak
- giddiness or fainting
- weakness, strange feeling, or numbness in any part of the body

<invented name> and cancer

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 <invented name> you may have unexpected bleeding (bleeding outside the gap week). 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 gap week

If you have taken all the 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 <invented name>

Always tell your doctor which medicines or herbal products you are already using. Also tell any other doctor or dentist who prescribes another medicine (or the pharmacist) that you use <invented name>. They can tell you if you need to take additional contraceptive precautions (for example condoms) and if so, for how long.

Some medicines can make <invented name> 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 infections (ritonavir, nelfinavir) or other infections (antibiotics such as griseofulvin, penicillin, tetracycline)
 - high blood pressure in the blood vessels in the lungs (bosentan)
- the herbal remedy St. John's wort

<invented name> 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)

Troleandomycin may increase the risk of intrahepatic cholestasis during coadministration with COCs.

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

Tell your doctor or pharmacist if you are using, have recently used or might use any other medicines

Laboratory tests

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

Pregnancy

If you are pregnant, do not take <invented name>. If you become pregnant while taking <invented name> stop immediately and contact your doctor. If you want to become pregnant, you can stop taking <invented name> at any time (see also "If you want to stop taking <invented name>").

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

Breast-feeding

Use of <invented name> is general 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.

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

Driving and using machines

There is no information suggesting that the use of <invented name> affects driving or use of machines.

<INVENTED NAME> contains lactose

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

3. How to take <INVENTED NAME>

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

Take one tablet of <invented name> 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.

The strip contains 21 tablets. Along with blisters, there are enclosed stickers with the days of the week. Pick the day label that starts with the first day of your pill intake. Place the strip on the blister card over the words "Place day label here". Each day will line up with a row of pills. It is important to take your pill every day. And take the first tablet of the first row where the word "START" is indicated. Follow the direction of the arrow indicated on the strip until you have taken all 21 tablets.

Then take no tablets for 7 days. In the course of these 7 tablet-free days (otherwise called a stop or gap week) bleeding should begin. This so-called "withdrawal bleeding" usually starts on the 2nd or 3rd day of the week.

On the 8th day after the last <invented name> tablet (that is, after the 7-day gap week), 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 <invented name> in this manner, you are also protected against pregnancy also during the 7 days when you are not taking a tablet.

When can you start with the first strip

- *If you have not used a contraceptive with hormones in the previous month*
Begin with <invented name> on the first day of the cycle (that is the first day of your period). If you start <invented name> 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 another combined hormonal contraceptive, or combined contraceptive vaginal ring or patch*
You can start <invented name> 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 (from an implant or the IUD on the day of its removal, from an injectable when the next injection would be due) but in all of these cases you must use extra protective measures (for example, a condom) for the first 7 days of tablet-taking.
- *After a miscarriage or an abortion*
Follow the advice of your doctor.
- *After having a baby*
You can start <invented name> between 21 and 28 days after having a baby. If you start later than day 28, use a so-called barrier method (for example, a condom) during the first seven days of <invented name> use.
If, after having a baby, you have had sex before starting <invented name> (again), be sure that you are not pregnant or wait until your next period.
- *If you are breastfeeding and want to start <invented name> (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 <invented name> than you should

There are no reports of serious harmful results of taking too many <invented name> tablets. If you take several tablets at once then you may have symptoms of nausea or vomiting. Young girls may have bleeding from the vagina.

If you have taken too many <invented name> tablets, or you discover that a child has taken some, ask your doctor or pharmacist for advice.

If you forget to take <invented name>

- If you are **less than 12 hours late** taking a tablet, the protection from pregnancy is not reduced. Then still 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 from pregnancy may be reduced. The greater the number of the tablets that you have forgotten, the greater is the risk that the protection from pregnancy is reduced.

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

- **More than 1 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 may be pregnant. In that case, contact your doctor.

- **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.

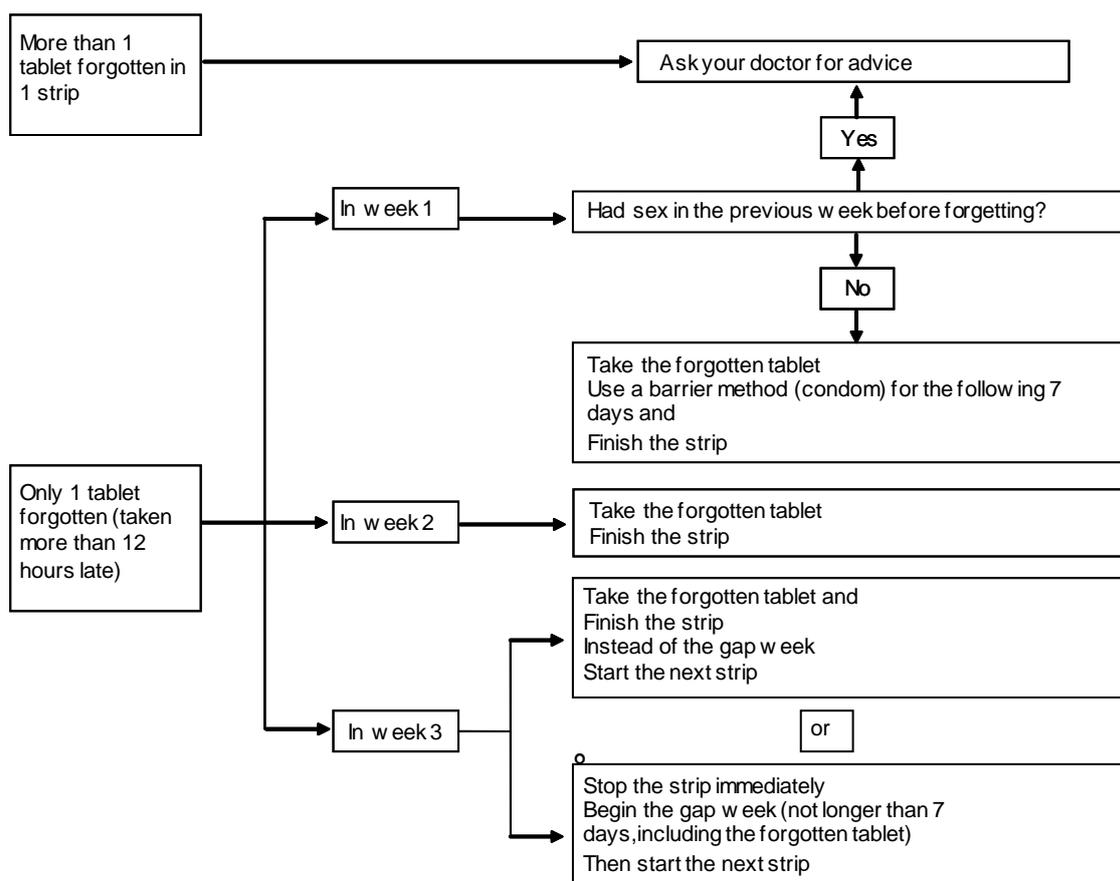
- **One tablet forgotten in week 3**

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 tablet-free period start the next strip. Most likely, you will have a period at the end of the second strip but you may have light or menstruation-like bleeding during the second strip.
2. You can also stop the strip and go directly to the tablet-free period of 7 days (**record the day on which you forgot your tablet**). If you want to start a new strip on the day you always start, make the tablet-free period 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 first tablet-free period, you may be pregnant. Contact your doctor before you start the next strip.



What to do in the case of vomiting or severe diarrhoea

If you vomit within 3-4 hours after taking a 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 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 <invented name>”.

Delaying your period: what you need to know

Even though it is not recommended, you can delay your period by going straight to a new strip of <invented name> instead of the tablet-free period and finishing it. You may experience light or menstruation-like bleeding while using this second strip. After the usual tablet-free period of 7 days, *start* the next strip.

You might 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 tablet-free week*. If you have to change this day, reduce the number of tablet-free days (*but never increase them - 7 is the maximum!*). For example, if your tablet-free days normally begin 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 tablet-free 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 how to proceed, contact your doctor for advice.

If you want to stop taking <invented name>

You can stop taking <invented name> 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 <invented name> 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 product, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

The following is a list of the side effects that have been linked with the use of <invented name>.

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

- mood swings, depression
- headache
- nausea, abdominal pain (stomach ache)
- breast pain or tenderness
- weight increase

Uncommon side effects (between 1 and 10 in every 1,000 users may be affected):

- decreased interest in sex
- skin rash
- migraine
- vomiting, diarrhoea
- itching or raised bumps on the skin
- swollen breasts
- fluid retention

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

- contact lens intolerance
- allergic reactions
- increased interest in sex
- breast or vaginal discharge
- erythema nodosum (characterized by painful reddish skin nodules)
- erythema multiform (rash with target-shaped reddening or sores)
- weight decrease

The following serious adverse events have been reported slightly more often in women using contraceptive pills (see Section 2: When to take special care with <invented name>?)

- venous or arterial blood clots
- stroke
- high cholesterol
- changes in glucose tolerance
- golden brown pigment patches (chloasma), so called “pregnancy patches”,
- raised blood pressure
- liver tumours or breast cancer
- disturbances of liver function

The following conditions may occur or get worse with combined oral contraceptives:

Crohn’s disease, ulcerative colitis, epilepsy, migraine, endometriosis, porphyria (metabolism disorder which causes abdominal pains and mental disorders), systemic lupus erythematosus (where the body attacks and injures its own organs and tissues), herpes in late pregnancy, Sydenham's chorea (rapid involuntary jerking or twitching movements), haemolytic uraemic syndrome (a condition which occurs after diarrhoea caused by *E.coli*), liver problems shown by jaundice, gall bladder disorders or gallstone formation.

In women with hereditary exogenous angioedema, the oestrogens in contraceptive pills may induce or exacerbate symptoms of angioedema.

If you get any side effects, talk to your doctor or pharmacist or nurse. This includes any side effects not listed in this leaflet. You can also report side effects directly via the national reporting. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store <INVENTED NAME>

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 <invented name> carton and blister 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 <invented name> contains

The active substances are levonorgestrel and ethinylestradiol.

Each tablet contains 0.10 mg of levonorgestrel and 0.02 mg of ethinylestradiol. The other ingredients (excipients) are anhydrous lactose, povidone K-30 (E1201), magnesium stearate (E572) and opadry II pink [polyvinyl alcohol, talc (E553b), titanium dioxide (E171), polyethylene glycol 3350, red aluminium lake (E129), lecithin (E322), iron oxide red (E172) and blue aluminium lake (E1329)].

What <invented name> looks like and contents of the pack

- Each film-coated tablet is pink and rounded.
- <invented name> is available in strips (blisters) of 21 tablets.
- Pack sizes are of 1, 3 or 6 strips, each strip with 21 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.
Polígono Industrial Navatejera, La Vallina S/N
24008 Navatejera (Leon) - Spain

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

Portugal: Effilevo
Spain: Levobel
France: Effilevo
Italy: Effilevo

This leaflet was last revised in <{MM/YYYY}>

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