

Package Leaflet: Information for the user

Erlidona 0.10 mg/0.02 mg film-coated tablet

Levonorgestrel / Ethinylestradiol

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 further questions, please 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, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Erlidona is and what it is used for
2. What you need to know before you take Erlidona
3. How to take Erlidona
4. Possible side effects
5. How to store Erlidona
6. Contents of the pack and other information

1. What Erlidona is and what it is used for

Erlidona is a contraceptive pill and it is 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.’ Erlidona is called a “low-dose” contraceptive pill because it contains only a small amount of hormones.

2. What you need to know before you take Erlidona

General notes

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

Erlidona, 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.

Do not use Erlidona:

- 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 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 have stopped menstruating, possibly due to exercise or diet
- 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.
- if you have hepatitis C and are taking the medicinal products containing ombitasvir/paritaprevir/ritonavir and dasabuvir (see also in section “Other medicines and Erlidona”).

Warnings and precautions

In some situations you need to take special care while using Erlidona 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 Erlidona. Also, if any of the following applies or if any of the conditions develops or worsens while you are using Erlidona 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 “Erlidona 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.

Erlidona and venous and arterial blood clots

The use of any combination pill, including Erlidona, increases a woman's risk of developing a **venous blood clot (venous thrombosis)** compared with women who do not take any contraceptive pill. The excess risk is highest during the first year a woman ever uses a combined 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 Erlidona 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 Erlidona, 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 Erlidona, especially if you are older than 35 years.**
- 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 Erlidona 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
- difficulty controlling your movements
- sudden severe stomach ache

Erlidona 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.

Cervical cancer in long-term users has been reported, but it is not clear if it is contributed by sexual behaviour or other factors such as human papilloma virus (HPV).

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 Erlidona 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 Erlidona

Always tell your doctor which medicines or herbal products you are already using or have recently taken, including medicines obtained without a prescription. Also tell any other doctor or dentist who prescribes another medicine (or the pharmacist) that you use Erlidona. 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 Erlidona 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, topiramate, felbamate)
 - tuberculosis (e.g. rifampicin)
 - HIV infections (ritonavir, nelfinavir, nevirapine) or other infections (such as griseofulvin)
 - high blood pressure in the blood vessels in the lungs (bosentan)
- the herbal remedy St. John's wort

Erlidona 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.

Do not use Erlidona 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.

Erlidona can be restarted approximately 2 weeks after completion of this treatment. See section "Do not use Erlidona".

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

Erlidona with food and water

Erlidona may be taken with or without food, if necessary with a small amount of water

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 and breast-feeding

If you are pregnant, do not take Erlidona. If you become pregnant while taking Erlidona stop immediately and contact your doctor. If you want to become pregnant, you can stop taking Erlidona at any time (see also “If you want to stop taking Erlidona”).

Use of Erlidona 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 this medicine.

Driving and using machines

There is no information suggesting that the use of Erlidona affects driving or use of machines.

Erlidona contains lactose, red aluminium lake (E129) and soya lecithin

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

The film-coated of Erlidona contains red aluminium lake (E129) and soya lecithin which may cause allergic reactions. If you are allergic to peanut or soya, do not use this medicinal product.

3. How to take Erlidona

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 the first tablet out of one of the sections marked with the corresponding day of the week (e.g. “MON” for Monday). Take the tablets every day at approximately the same time, with a little water if necessary, in the order shown on the blister pack. Take one tablet daily for 21 consecutive days. Start a new pack after a 7-day tablet-free interval, during which time withdrawal bleeding (a period) usually occurs. Withdrawal bleeding, which is similar to a period, will appear two or three days after taking the last tablet and it may not have finished before starting the next pack.

If you use Erlidona 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 Erlidona on the first day of the cycle (that is the first day of your period). If you start Erlidona 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 Erlidona 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 Erlidona 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 Erlidona use.
If, after having a baby, you have had sex before starting Erlidona (again), be sure that you are not pregnant or wait until your next period.
- If you are breastfeeding and want to start Erlidona (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 Erlidona than you should

There are no reports of serious harmful results of taking too many Erlidona 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 Erlidona tablets, or you discover that a child has taken some, ask your doctor or pharmacist for advice.

If you forget to take Erlidona

- 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.

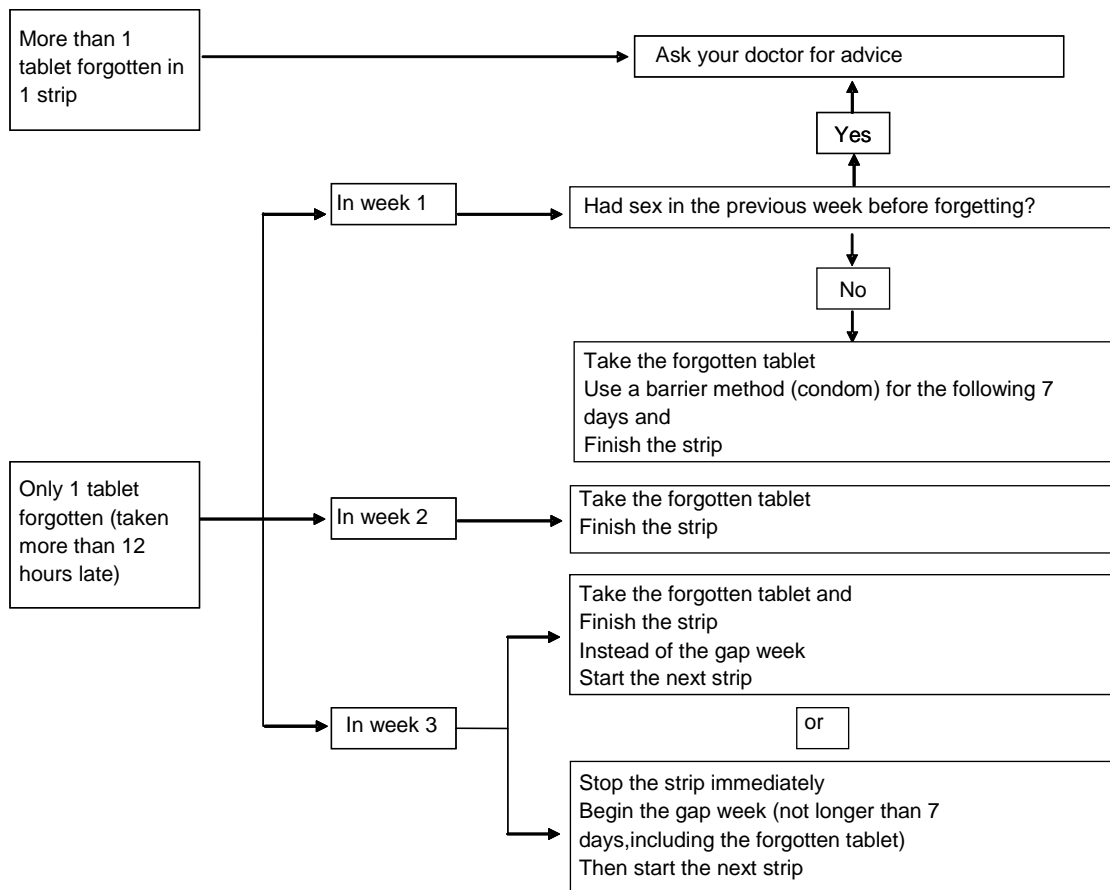
- **One tablet forgotten in week 3**

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 Erlidona”.

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 Erlidona 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 Erlidona

You can stop taking Erlidona 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 Erlidona 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, 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 Erlidona.

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

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

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

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

Rare side effects (may affect up to 1 in 1,000 women):

- 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: Warnings and precautions)

- 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, uterine myoma, 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.

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via HPRA Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: www.hpra.ie; E-mail: medsafety@hpra.ie. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Erlidona

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 Erlidona 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 Erlidona 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 coating system [polyvinyl alcohol, talc (E553b), titanium dioxide (E171), polyethylene glycol 3350, red aluminium lake (E129), soya lecithin (E322), iron oxide red (E172) and blue aluminium lake (E132)].

What Erlidona looks like and contents of the pack

Each film-coated tablet is pink and rounded.

Erlidona is available in strips (calendar 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

Actavis Group PTC ehf.
Reykjavíkurvegur 76-78
220 Hafnarfjörður
Iceland

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:

Netherlands Levonorgestrel/Ethinylestradiol Actavis 0.10 mg / 0.02 mg, filmomhulde tabletten

France Erlidona, comprimé pelliculé

Germany Eulitop 0,10 mg/0,02 mg Filmtabletten

Ireland Erlidona

Italy Levonorgestrel e Etinilestradiolo Aurobindo Pharma Italia

Portugal Levonorgestrel + Etinilestradiol Aurovitas

Spain Levonorgestrel/Etinilestradiol Aurobindo 0,1 mg/0,02 mg comprimidos recubiertos con película EFG

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