

PACKAGE LEAFLET: INFORMATION FOR THE USER

Levest 150/30 Coated Tablets

Levonorgestrel 150 micrograms & Ethinylestradiol 30 micrograms

Read all of this leaflet carefully before you start using this medicine.

- 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. Do not pass it on to others. It may harm them.
- If any of the side effects get serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

In this leaflet:

1. What Levest is and what it is used for
2. Before you take Levest
3. How to take Levest
4. Possible side effects
5. How to store Levest
6. Further information

1. WHAT LEVEST IS AND WHAT IT IS USED FOR

Levest coated tablets are a combined oral contraceptive and belongs to a group of products often referred to as “the Pill”. Levest contains two hormones: Oestrogen (Ethinylestradiol) and progestogen (Levonorgestrel). These hormones prevent you from getting pregnant, just as your natural hormones would prevent you from conceiving again when you are already pregnant.

2. BEFORE YOU USE LEVEST

General notes

Before you can begin taking Levest your doctor will ask you some questions about your personal health 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 Levest, or where the reliability of Levest may be decreased. In such situations you should either not have intercourse 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 Levest alters the monthly changes of the cervical mucus.

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

Do not take Levest

- If you are allergic (hypersensitive) to any of the ingredients of Levest.
- If you have (or have had in the past) a blood clot (thrombosis) in a blood vessel of the leg, lung (embolus) or other organs.
- If you have (or have had in the past) a heart attack or stroke.
- If you have (or have had in the past) a disease that can be a predictor of a heart attack (for example, angina pectoris, which causes severe pain in the chest) or of a stroke (for example, a transient slight stroke with no residual effects).
- If you have a disease that may increase the risk of a thrombosis in the arteries. This applies to the following diseases:
 - Diabetes mellitus 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 (had) a certain form of migraine (with so-called focal neurological symptoms).
- If you have (had) an inflammation of the pancreas (pancreatitis).
- If you have or have had in the past a liver disease and your liver function is still not normal.
- If you have or have had a tumour in the liver.
- If you have (had) or if you are suspected to having breast cancer or cancer of the genital organs.
- If you have any unexplained bleeding from the vagina.
- If you have absence of menstrual period and the cause is unknown.

Take special care with Levest

In some situations you need to take special care while using Levest or any other combined hormonal contraceptive, and it may be necessary that you are regularly checked by your doctor. If any of the following conditions apply to you, you must inform your doctor before starting to use Levest. Also if any of the following conditions develops or worsens during the use of Levest you must consult your doctor.

- If a close relative has or has 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 ulcerative colitis (inflammatory bowel disease).

- If you have HUS (haemolytic uremic syndrome; a blood disease that causes kidney damage).
- If you have epilepsy (see “Taking other medicines”).
- If you have SLE (systemic lupus erythematosis; a disease of the immune system).
- If you have a disease that first appeared during pregnancy or earlier use of sex hormones (for example, hearing loss, porphyria (a disease of the blood), gestational herpes (skin rash with vesicles during pregnancy), Sydenham's chorea (a disease of the nerves in which sudden movements of the body occur).
- If you have or have ever had chloasma (golden brown pigment patches, so called “pregnancy patches”, especially on the face). If this is the case, avoid direct exposure to sunlight or ultraviolet light.
- If you have hereditary angioedema, products containing oestrogens may induce or worsen symptoms of angioedema. You should see your doctor immediately if you experience symptoms of angioedema such as swollen face, tongue and/or pharynx and/or difficulty swallowing or hives together with difficulty breathing.
- If a pre-existing high blood pressure condition worsens.
- If a pre-existing high level of fat in blood worsens.

Levest and thrombosis

Venous thrombosis

The use of any combination pill, including Levest, increases a woman's risk of developing a venous thrombosis (formation of a blood clot in vessels) compared with a woman who does not take any (contraceptive) pill.

The risk of venous thrombosis in users of combined pills increases:

- With increasing age.
- If you are overweight.
- If one of your close relatives has had a blood clot (thrombosis) in the leg, lung, or other organ at a young age.
- If you must have an operation (surgery), any prolonged period of immobilisation, or if you have had a serious accident. It is important to tell your doctor in advance that you are using Levest as the treatment may have to be stopped. Your doctor will tell you when to start again. This is usually about two weeks after you are back on your feet.

Arterial thrombosis

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

The risk of arterial thrombosis in users of combined pills increases:

- With increasing age.
- **If you smoke you are strongly advised to stop smoking when you use Levest, especially if you are older than 35 years.**
- If you have an increased fat content in your blood (cholesterol or triglycerides).
- If you have high blood pressure.
- If you have migraine.
- If you have a problem with your heart (valve disorder, a disturbance of the heart rhythm).

Stop taking Levest and tell your doctor immediately if after taking Levest you notice possible signs of thrombosis, such as

- any unusual, severe or long-lasting headache or worsening of migraine.
- partial or complete blindness or double vision.
- sudden pain and/or swelling in one of your legs.
- sudden breathlessness.
- sudden cough without an obvious cause.
- sudden severe pain in the chest which may reach the left arm.
- difficulty in speaking or inability to speak.
- weakness, strange feeling, or numbness in any part of the body.
- a feeling of dizziness or spinning.
- collapse with or without focal seizure.
- motor disturbances.
- sudden severe abdominal pain.

Levest and cancer

Breast cancer has been observed slightly more often in women using combined 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 combined 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 lumps.

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 unusual severe abdominal pain.

Bleeding between periods

During the first few months that you are taking Levest, you may have unexpected bleeding (bleeding outside the gap week). If this bleeding lasts longer than a few months, or if it begins after some months, your doctor must investigate the cause.

What you must do if no bleeding occurs in 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.

Taking other medicines

Always tell the doctor, who prescribes Levest, which medicines or herbal products you are already using. Also tell any other doctor or dentist who prescribes another medicine (or the dispensing pharmacist) that you are using Levest. 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 Levest less effective in preventing pregnancy, or can cause unexpected bleeding. They include medicines used for the treatment of epilepsy (e.g., primidone, phenytoin, barbiturates, carbamazepine, oxcarbamazepine, topiramate, felbamate) and tuberculosis (e.g. rifampicin), or HIV infections (ritonavir, nevirapine) or other infectious diseases (griseofulvin, penicillin, tetracycline), medicines that increase the motility of your intestines (metoclopramide), and the herbal remedy St. John's wort.
- Levest may influence the effect of other medicines, e.g. medicines containing cyclosporin, or the anti-epileptic lamotrigine (this could lead to an increased frequency of seizures).

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

Effect on 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 become pregnant while taking Levest you must stop immediately and contact your doctor.

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

Breast feeding

Use of Levest 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.

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

Driving and using machines

Levest does not have any known effect on your ability to drive or use machines.

Important information about some of the ingredients of Levest

Levest contains **lactose** and **sucrose**. 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 LEVEST

Always take Levest exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

Take one tablet of Levest 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. Next to each tablet is printed the day of the week that it should be taken. If, for example you start on a Wednesday, take a tablet with “WED” next to it. Follow the direction of the arrow on the strip until all 21 tablets have been taken.

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 gap week.

On the 8th day after the last Levest tablet (that is, after the 7-day gap week), start the following strip, even if the bleeding has not stopped. This means that you should start the following strip on the same day of the week and that the withdrawal bleed should occur on the same days each month.

If you use Levest in this manner, you are also protected against pregnancy during the 7 days that you are not taking a tablet.

Starting the first pack of Levest

- If you have not used a contraceptive with hormones in the previous month.

Begin with Levest on the first day of the cycle (that is the first day of your menstruation). If you start Levest on the first day of your menstruation 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 Levest preferably on the day after the last active tablet (the last tablet containing the active substance) of your previous pill, but at the latest on the day after the tablet-free days of your previous pill finish (or after the last inactive tablet of your previous pill). When changing from a combined 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. Follow the advice of your doctor.

- After having a baby.

After having a baby, you can start Levest between 21 and 28 days later. If you start later than day 28, you must use a so-called barrier method (for example, a condom) during the first seven days of Levest use. If, after having a baby, you have had intercourse before starting Levest (again), you must first be sure that you are not pregnant or you must wait until the next menstrual bleed.

Let your doctor advise you in case you are not sure when to start.

- If you are breastfeeding and want to start Levest after having a baby.

Read the section on "Breast feeding".

If you take more Levest than you should

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

If you forget to take Levest

If you are **less than 12 hours late** in taking your pill, the protection from pregnancy is not reduced. Take the tablet as soon as you remember, and further pills 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 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:

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. Take the tablets again at the usual time and use **extra precautions** for the next 7 days, for example, a condom. If you have had intercourse in the week before the oversight or you have forgotten to start a new strip after the tablet-free period, you must realise that there is a risk of pregnancy. 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. Take the tablets again at the usual time. The protection from pregnancy is not reduced, given that you have taken the tablets correctly in the previous 7 days, otherwise extra precaution should be used for the next 7 days.

One tablet forgotten in week 3

You can choose between two possibilities:

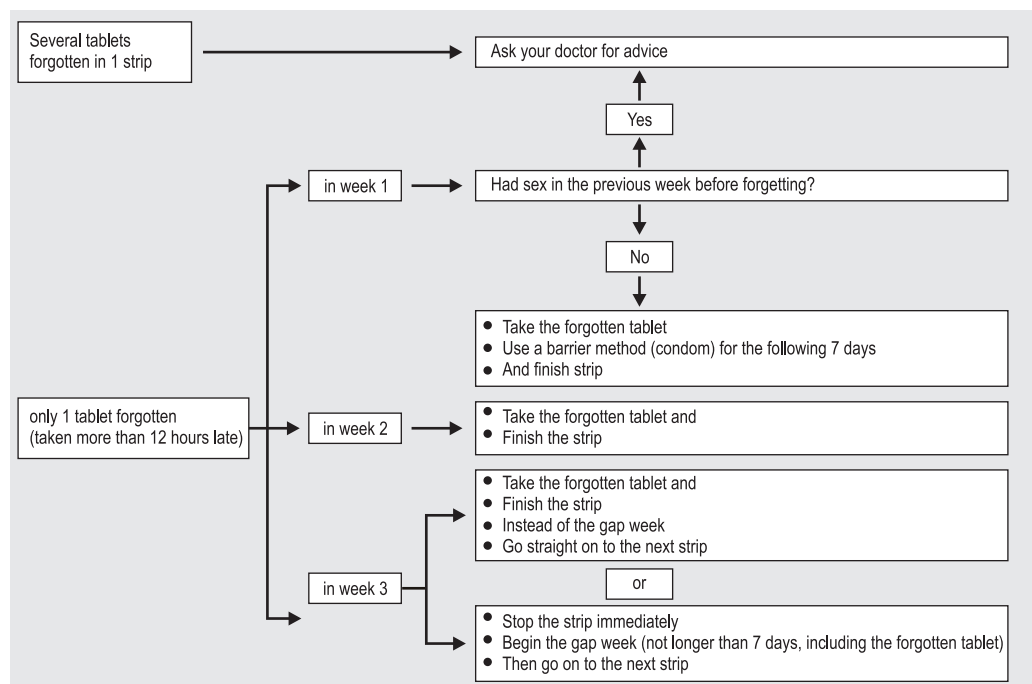
1. Take the forgotten tablet as soon as you remember, even if that means that you have to take two tablets at the same time. Take the tablets again at the usual time. Instead of the tablet-free period go straight on to the next strip.

Most likely, you will have a period (withdrawal bleed) at the end of the second strip but you may also have spotting or breakthrough 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 your fixed start day, make the tablet-free period less than 7 days.

If you follow either 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 bleeding in the first tablet-free period, this may mean that you are pregnant. You must contact your doctor before you go on to the next strip.



What must you do in the case of vomiting or severe diarrhoea

If you vomit within 3-4 hours of taking a tablet or you have severe diarrhoea, there is a risk that the active substances in the pill are not fully adsorbed into your body. The situation is similar to if you forget a tablet. After vomiting or diarrhoea, you must 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 this is not possible or 12 hours have passed, you should follow the advice given under 'if you forget to take Levest.'

Delay of menstrual period: what must you know

Even if not recommended, delay of your menstrual period (withdrawal bleed) is possible by going straight on to a new strip of Levest instead of the tablet-free period, to the end of the second strip. You may experience spotting (drops or flecks of blood) or breakthrough bleeding while using the second strip. After the usual tablet-free period of 7 days, continue with the following strip.

You might ask your doctor for advice before deciding to delay your menstrual period

Change of the first day of your menstrual period: what you must know

If you take the tablets according to the instructions, then your menstrual period/withdrawal bleed will begin in the tablet-free week. If you have to change this day, do this by making the tablet-free period shorter (but never longer!) For example, if your tablet-free period begins on a Friday, and you want to change this to a Tuesday (3 days earlier) you must start a new strip 3 days earlier than usual. If you make the tablet-free period very short (for example, 3 days or less) then it may be that you do not have any bleeding during this tablet-free period. You may then experience spotting (droplets or flecks of blood) or breakthrough bleeding.

If you are not sure how to proceed, contact your doctor for advice.

If you want to stop taking Levest

You can stop taking Levest 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 have any further questions on the use of this product, ask your doctor or pharmacist.

4. POSSIBLE SIDE EFFECTS

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

Common side effects (affecting more than 1 in 100, but less than 1 in 10 women):

Mood swings, headache, abdominal pain (stomach ache), acne, breast pain, weight gain, nausea.

Uncommon side effects (affecting more than 1 in 1000 but less than 1 in 100 women):

Vomiting, diarrhoea, fluid retention, migraine, decreased libido (interest in sex), breast enlargement, itchy red rash of the skin (urticaria).

Rare side effects (affecting less than 1 in 1000 women):

Contact lens intolerance, allergic reactions, weight loss, increased libido (interest in sex, breast discharge, vaginal discharge, allergic reactions which can sometimes be severe with swelling of the skin and/or mucous membranes (erythema nodosum & erythema multiforme).

Other serious side effects you should be aware of are also mentioned in section 2 of this leaflet (**Do not take Levest & Take special care with Levest**). These include:

- Blood clot disorders,
- High blood pressure,
- Liver tumors,
- Swelling of the skin (angioedema),
- Occurrence or deterioration of conditions such as: Crohn's disease, epilepsy, migraine etc.

If any of the side effects get serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

5. HOW TO STORE LEVEST

Keep out of the sight and reach of children.

Store below 25° C.

Do not use Levest after the expiry date which is stated on the carton.

The expiry date refers to the last day of that month.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. FURTHER INFORMATION

Levest contains

- The active substances are Levonorgestrel (150µg) and Ethinylestradiol (30µg).
- The other ingredients are Lactose monohydrate, maize starch, povidone k-25, sucrose, talc, calcium carbonate, povidone k-90, glycerin, macrogol 6000, titanium dioxide, magnesium stearate, carnauba wax.

What Levest looks like and contents of the pack

Levest tablets are white, circular, biconvex and sugar coated.

Each blister pack contains 21 tablets.

Levest is sold in cartons of 1, 3, 6 or 13 blister packs.

Not all pack sizes may be marketed.

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