

## **PACKAGE LEAFLET: INFORMATION FOR THE USER**

### **Levest 150/30 microgram Coated Tablets**

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 any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them.
- If you get any side effects, talk to your doctor or pharmacist. This includes any side effects not listed in this leaflet. See section 4.

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

1. What Levest is and what it is used for
2. What you need to know before you take Levest
3. How to take Levest
4. Possible side effects
5. How to store Levest
6. Contents of the pack and other 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. What you need to know before you take 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 taking 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 body temperature and 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 ethinylestradiol or levonorgestrel or any of the other ingredients of this medicine (listed in section 6).
- 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 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 (or have ever had) a certain form of migraine (with so-called focal neurological symptoms).
- 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 to having breast cancer or cancer of the genital organs.
- If you have any unexplained bleeding from the vagina.
- If you have hepatitis C and are taking the medicinal products containing ombitasvir/paritaprevir/ritonavir and dasabuvir (see also in section “Other medicines and Levest”).

### **Warnings and precautions**

In some situations you need to take special care while taking 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 uraemic syndrome; a blood disease that causes kidney damage).
- If you have epilepsy (see section “Other medicines and Levest”).
- If you have SLE (systemic lupus erythematosus; 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 throat and/or difficulty

- swallowing or hives together with difficulty breathing.
- If you have a blood disease called sickle cell anaemia.
  - If a pre-existing high blood pressure condition worsens.
  - If a pre-existing high level of fat in blood worsens.

Talk to your doctor or pharmacist before taking Levest.

## **Levest and venous and arterial blood clots**

### Venous blood clots

The use of any combination pill, including Levest increases a woman's risk of developing a **venous blood clot or venous thrombosis** (formation of a blood clot in vessels) compared with a woman who does not take any (contraceptive) pill. The excess risk is highest during the first year a woman initially starts using a combination pill or when she restarts use after a pill-free interval of at least a month.

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.

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 Levest, 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.

### Arterial blood clots

The use of combination pills has been connected with an increase of the risk of **arterial blood clot or 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 are overweight.
- If one of your close relatives ever had a heart attack or stroke at a young age.
- 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 contact your doctor immediately if after taking Levest you notice possible signs of a blood clot, such as:**

- any unusual, severe or long-lasting headache or worsening of migraine.
- partial or complete blindness or double vision.
- severe 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.
- weakness, strange feeling, or numbness in any part of the body.
- 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.

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 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, talk to your doctor, who will 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 a row, 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 Levest**

Always tell the doctor, who prescribes Levest, if you are taking, have recently taken or might take any other medicines, including herbal products. Also tell any other doctor or dentist who prescribes another medicine (or the pharmacist) that you take 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, oxcarbazepine, topiramate and felbamate),
- tuberculosis (e.g. rifampicin),
- HIV infections (ritonavir, nevirapine) or other infectious diseases (griseofulvin),
- High blood pressure in the blood vessels in the lungs (bosentan),
- the herbal remedy St. John's wort.

Levest may influence the effect of other medicines, for example:

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

Do not take Levest 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.

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

### **Levest with food and drink**

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

### **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 and breast-feeding**

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.

#### Pregnancy

If you are pregnant, do not take Levest. If you become pregnant while taking Levest you must stop immediately and contact your doctor. If you want to become pregnant, you can stop taking the pill at any time (see also section "If you want to stop taking Levest").

#### 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.

### **Driving and using machines**

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

**Levest contains lactose and sucrose**

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. Remember to take Levest as prescribed because missing tablets could reduce the effectiveness of the medicine.

Take one tablet of Levest every day, if necessary with a small amount of water. 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 2<sup>nd</sup> or 3<sup>rd</sup> day of the gap week.

On the 8<sup>th</sup> 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 take 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 any 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.
- **While breast-feeding**  
If you are breast-feeding and want to start taking Levest (again) after having a baby, read the section “Pregnancy and breast feeding”.

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

#### **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 then continue to take following pills at the usual time (even if this means taking two tablets the same day). In this case you do not need to use any additional method of contraception.

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.

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

- **If you forgot more than one tablet in this strip**  
Contact your doctor.
- **If you forgot one tablet 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.

- **If you forgot one tablet 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.

- **If you forgot one tablet in week 3**

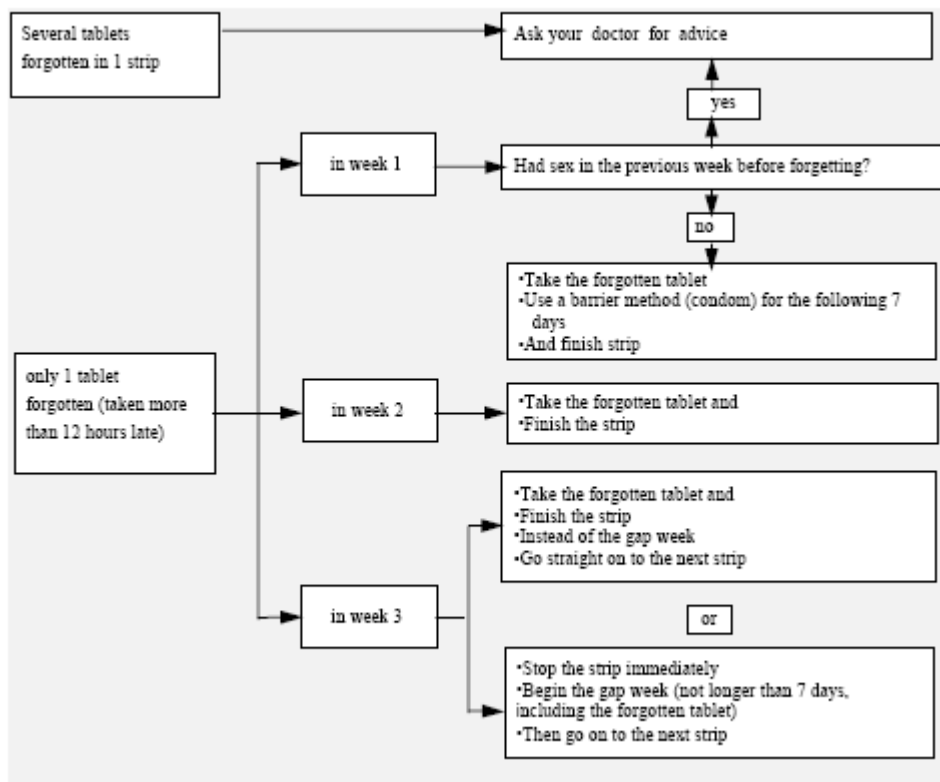
You can choose between two options:

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 any of the above 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 to do if you vomit or have 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 almost 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.'

### Delaying your period: what you need to 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 want to become pregnant, stop taking Levest and wait for a menstrual 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 Levest:

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

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

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

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

**Rare** (may affect up to 1 in 1,000 people):

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).

**Very rare** (may affect up to 1 in 10,000 people):

Inflammation of large intestine (ischaemic colitis) and inflammation of the pancreas.

**Not known** (frequency cannot be estimated from the available data):

Hepatocellular injury (e.g. hepatitis, hepatic function abnormal).

**Oral contraceptive use has been associated with:**

- Increased risk of blood clots in arteries and veins and disorders caused by a blood clot that breaks loose, including heart attack, blood clot in a vein and blood clot in the lung (see section “Warnings and precautions”).
- Increased risk of changes in the surface of the neck of the uterus (intraepithelial neoplasia) and cancer of the neck of the uterus.
- Increased risk of breast cancer diagnosis (see section “Warnings and precautions”).

**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 Yellow Card Scheme, Website: [www.mhra.gov.uk/yellowcard](http://www.mhra.gov.uk/yellowcard) or search for MHRA Yellow Card in the Google Play or Apple App Store.

By reporting side effects you can help provide more information on the safety of this medicine.

## **5. How to store Levest**

Keep this medicine 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 after 'EXP'. The expiry date refers to the last day of that month.

Do not throw away the 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 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 and 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.

### **Marketing Authorisation Holder**

Morningside Healthcare Ltd.

115 Narborough Road

Leicester

LE3 0PA

UK

### **Manufacturer**

Morningside Pharmaceuticals Ltd.

5 Pavilion Way, Castle Business Park,

Loughborough, Leicestershire,

LE11 5GW, UK

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