

Package leaflet: Information for the user

Ethinylestradiol/levonorgestrel Teva 0,02 mg/0,1 mg, filmomhulde tabletten 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 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 possible side effects not listed in this leaflet. See section 4.

What is 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 do you need to take special care with <invented name>
 - <invented name> and thrombosis
 - <invented name> and cancer
 - Bleeding between periods
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 - Important information about some of the ingredients of <invented name>
3. How to take <invented name>
 - When you can start with the first strip
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 - What you must do in case of vomiting or severe diarrhoea
 - Delay of menstrual period: what you must know
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- If you want to stop taking <invented name>

4. Possible side effects

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6. Contents of the pack and other information

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 the <invented name> 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 <invented name> alters the monthly changes of the 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.

Do not take <invented name>

- if you have (or have had in the past) a blood clot (thrombosis) in a blood vessel of the leg, lungs (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 situations:
 - 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 (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 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 medicinal products containing ombitasvir/paritaprevir/ritonavir, dasabuvir, glecaprevir/pibrentasvir or sofosbuvir/velpatasvir/voxilaprevir (see also in section “Other medicines and <invented name>”).

Warnings and precautions

In some situations you need to take special care while using <invented name> 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 applies to you, you must inform your doctor before starting to use <invented name>. Also if any of the following conditions develops or worsens during the use of <invented name> 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 disorder that causes kidney damage)
- If you have sickle cell anaemia (an inherited disease of the red blood cells)
- If you have epilepsy
- If you have SLE (systemic lupus erythematosus; a disorder 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 experience symptoms of angioedema such as swollen face, tongue and/or throat and/or difficulty swallowing or hives potentially with difficulty breathing contact a doctor immediately. Products containing estrogens may cause or worsen the symptoms of hereditary and acquired angioedema.

<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 **blood clot of the vein (venous thrombosis)** compared with women who do not take any contraceptive pill.

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

- With increasing age
- If you are overweight
- If one of your close relatives had a blood clot in the leg, lung (pulmonary embolism), or other organ at a young age
- If you have surgery if you have had an serious accident or if you are immobilised for a long time. It is important to tell your doctor in advance that you are using <invented name> as the treatment may have to be stopped. Your doctor will tell you when to start <invented name> 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>, approximately 20 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 combinations pills has been connected with an increase of the risk of a **blood clot of the artery (arterial thrombosis)**, for example, in the blood vessels of the heart (heart attack) or the brain (stroke).

The risk of blood clots in an artery (arterial thrombosis) 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 years.**
- If you have high levels of blood cholesterol or triglycerides
- If you are overweight
- If one of your close relatives had an 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 cardiac rhythm)

Stop taking <invented name> and contact your doctor immediately if you notice possible signs of thrombosis, 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

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.

Psychiatric disorders

Some women using hormonal contraceptives including <invented name> have reported depression or depressed mood. Depression can be serious and may sometimes lead to suicidal thoughts. If you experience mood changes and depressive symptoms contact your doctor for further medical advice as soon as possible.

Other medicines and <invented name>

<invented name> 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 lump.

In rare cases, benign liver tumors, and in even fewer cases malignant liver tumors 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 <invented name>, 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.

Always tell the doctor, who prescribes <invented name>, 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 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, oxcarbamazepine, topiramate, felbamate) or migraine (topiramate)
- used for the treatment of tuberculosis (e.g. rifampicin), or HIV infections (ritonavir) or other infectious diseases (griseofulvin),
- to increase intestinal motility (e.g. metoclopramide)
- the herbal remedy St. John's wort.

If you want to use herbal products containing St. John's wort while you are already using <invented name> you should consult your doctor first.

- <invented name> may decrease the efficacy of other medicines, e.g.
 - medicines containing cyclosporinor
 - the anti-epileptic lamotrigine (this could lead to an increased frequency of seizures)

Do not use <invented name> if you have Hepatitis C and are taking medicinal products containing ombitasvir/paritaprevir/ritonavir, dasabuvir, glecaprevir/pibrentasvir or sofosbuvir/velpatasvir/voxilaprevir, as these products 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.

<invented name> can be restarted approximately 2 weeks after completion of this treatment. See section “Do not use <invented name>”.

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.

If you are pregnant, you must not take <invented name>. If you become pregnant while taking <invented name> you must 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>”).

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.

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.

<invented name> contains red aluminium lake (E 129)

It may cause allergic reactions.

3. How to take <invented name>

Take one tablet of <invented name> 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. It is marked with the days of the week on which each pill should be taken. Following the direction of the arrow printed on the strip you should take one pill each day for 21 days 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 gap week.

On the 8th day after the last <invented name> 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 <invented name> in this manner, you are also protected against pregnancy during the 7 days that 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 menstruation). If you start <invented name> 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 <invented name> on the day after the tablet-free period of your previous pill finished (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 or an abortion*
Follow your doctor's advice.
- *After having a baby*
After having a baby, you can start <invented name> 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 <invented name> use. If, after having a baby, you have had intercourse before starting <invented name> (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 breast-feeding and want to start <invented name> (again) after having a baby*
Read the section 2. on "Breast-feeding".

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 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. 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

sexual intercourse in the week before the oversight or you have forgotten to start a new strip after the tablet-free period, you must realize that there is a risk of pregnancy. In that case, contact your doctor.

contact your doctor before you go on to the next strip.

- **One tablet forgotten in week 2**

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

- **One tablet forgotten in week 3**

You can choose between 2 possibilities:

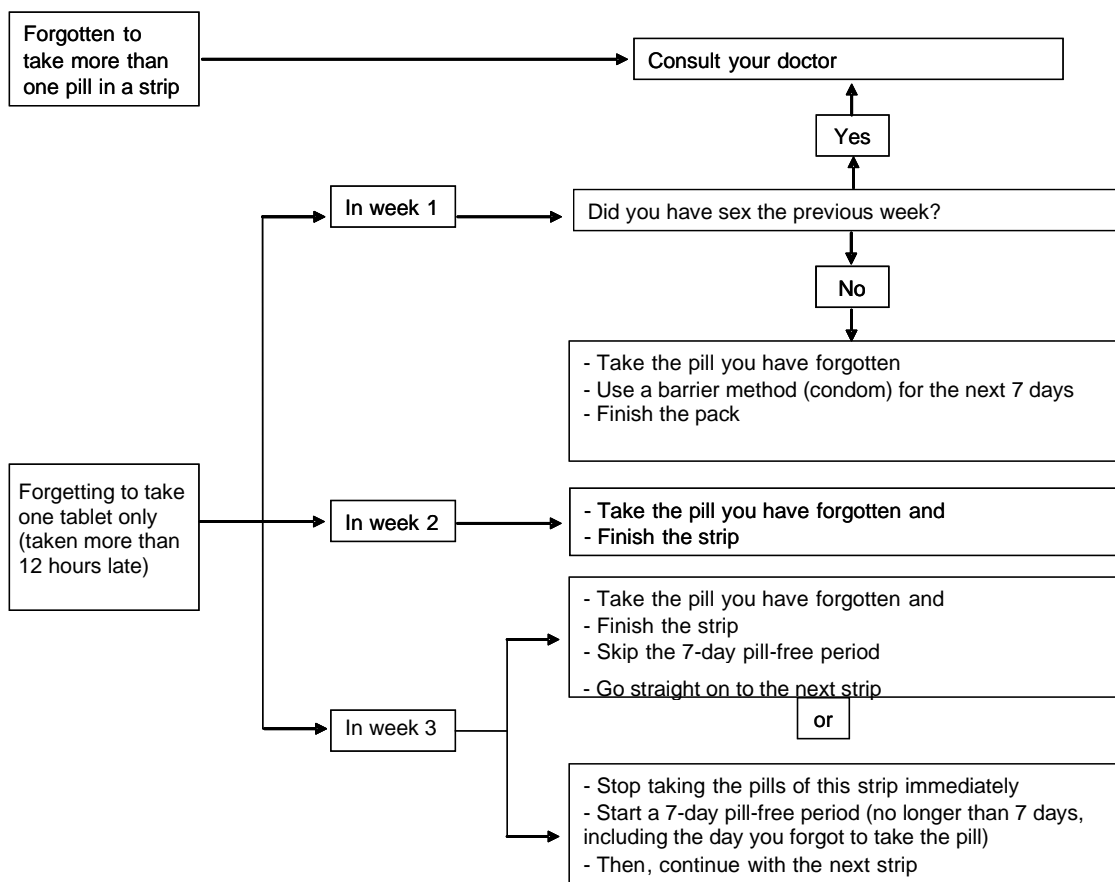
1. Take the forgotten tablet as soon as you remember, even if that means that you have to take two tablets at the same time. Take the tablets again at the usual time. Instead of the tablet-free period go straight on to the next strip.

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



What you must do in 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 tablet are not fully absorbed 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 tablet. If this is not possible or 12 hours have passed, you should follow the advice given under “If you forget to take <invented name>”.

Delaying of menstrual period: what you must know

Even if not recommended, delay of your period is possible by going straight on to a new strip of <invented name> instead of the tablet-free period, to the end of the second strip. You may experience light or menstruation-like bleeding while using this second strip. After the usual tablet-free period of 7 days, start with the next 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 period will begin in the tablet-free week on the same day. If you have to change this day, you 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 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 light or menstruation-like bleeding. *If you are not sure how what to do, 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 medicine, ask your doctor or pharmacist.

4. Possible side effects

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

Serious side effects

Contact a doctor immediately if you experience any of the following symptoms of angioedema: swollen face, tongue and/or throat and/or difficulty swallowing or hives potentially with difficulty breathing (see also section “Warnings and precautions”).

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

- **Common:** may affect up to 1 in 10 women: headache, mood changes (including depression), nausea, abdominal ache, painful breasts, tender breast, weight increase.
- **Uncommon:** may affect up to 1 in 100 women: vomiting, diarrhea, water retention or edema, migraine, less desire in sex, breast enlarged, rash, urticaria.
- **Rare:** may affect up to 1 in 1,000 women: irritation of the eyes during the use of contact lenses, hypersensitivity, weight decreased, breast discharge, vaginal discharge, libido increased, erythema nodosus (nodules on the

legs), erythema multiforme (skin lesions).

Reporting of side effects

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

5. How to store <invented name>

Keep out of the sight and reach of children.

Do not store above 30°C.

Do not use this medicine after the expiry date which is stated on the 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 are: lactose, povidone K-30 (E 1201), magnesium stearate (E 572) and opadry II pink [polyvinyl alcohol, talc (E 553b), titanium dioxide (E 171), polyethylene glycol 3350, red aluminium lake (E 129), lecithin (E 322), iron oxide red (E 172) and blue aluminium lake (E 132)].

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.

Houder van de vergunning voor het in de handel brengen en fabrikant

Houder van de vergunning voor het in de handel brengen

Teva Nederland B.V.
Swensweg 5
2031 GA Haarlem
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Fabrikant

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89143 Blaubeuren
Duitsland

Or

Laboratorios Leon Farma S.A.
C/La Vallina s/n
Poligono Industrial Navatejera
Villaquilambre, 24193
Spanje

Dit medicijn is geregistreerd in lidstaten van de Europese Economische Ruimte onder de volgende namen:

Duitsland: Liana-ratiopharm
Italië: Lestronette 0,10 mg + 0,02 mg
comprimé rivestite con film
Nederland: Ethinylestradiol/levonorgestrel
Teva 0,02/0,1 mg, filmomhulde tabletten

Deze bijsluiter is voor het laatst goedgekeurd in december 2023