Bijsluiter: Informatie voor de patiënt

Kosidina 0,060 mg/0,015 mg, filmomhulde tabletten

gestodene / ethinylestradiol

Important things to know about combined hormonal contraceptives (CHCs):
- They are one of the most reliable reversible methods of contraception if used correctly
- They slightly increase the risk of having a blood clot in the veins and arteries, especially in the first year or when restarting a combined hormonal contraceptive following a break of 4 or more weeks
- Please be alert and see your doctor if you think you may have symptoms of a blood clot (see section 2 “Blood clots”)

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, even if their signs of illness are the same as yours.
- 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 [nationally completed name] is and what it is used for

- [Nationally completed name] is an oral contraceptive pill and is used to prevent pregnancy.
- Each yellow tablet contains a small amount of two different female hormones, namely gestodene and ethinylestradiol.
- Each white tablet contains no active substances and are called placebo tablets.
- Contraceptive pills that contain two hormones are called “combination” pills.

2 What you need to know before you take [nationally completed name]

General notes
Before you start using [nationally completed name] you should read the information on blood clots in section 2. It is particularly important to read the symptoms of a blood clot – see Section 2 “Blood clots”).

Before you can begin taking[nationally completed 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[nationally completed name], or where the reliability of [nationally completed 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 [nationally completed name] alters the monthly changes of body temperature and of cervical mucus.

[nationally completed name]**, like other hormonal contraceptives, does not protect against HIV infection (AIDS) or any other sexually transmitted disease.**

Do not take [nationally completed name]

You should not use [nationally completed name] if you have any of the conditions listed below. If you do have any of the conditions listed below, you must tell your doctor. Your doctor will discuss with you what other form of birth control would be more appropriate.

- If you are allergic to ethinylestradiol or gestodene, or any of the other ingredients of this medicine (listed in section 6);
- This medicine contains lecithin (obtained from soya). If you are allergic to peanut or soya, do not use this medicine;
- If you have (or have ever had) a blood clot in a blood vessel of your leg (deep vein thrombosis, DVT), your lungs (pulmonary embolus, PE) or other organs;
- If you know you have a disorder affecting your blood clotting – for instance, protein C deficiency, protein S deficiency, antithrombin-III deficiency, Factor V Leiden or antiphospholipid antibodies;
- If you need an operation or if you are off your feet for a long time (see section 'Blood clots');
- If you have ever had a heart attack or a stroke;
- If you have (or have ever had) angina pectoris (a condition that causes severe chest pain and may be a first sign of a heart attack) or transient ischaemic attack (TIA – temporary stroke symptoms);
- If you have any of the following diseases that may increase your risk of a clot in the arteries:
  - severe diabetes with blood vessel damage
  - very high blood pressure
  - a very high level of fat in the blood (cholesterol or triglycerides)
  - a condition known as hyperhomocysteinaemia
- If you have (or have ever had) a type of migraine called 'migraine with aura';
- 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 unexplained bleeding from the vagina;
- If you have hepatitis C and are taking the medicines containing ombitasvir/paritaprevir/ritonavir, dasabuvir, glecaprevir / pibrentasvir or sofosbuvir/velpatasvir/voxilaprevir (see also in section 'Other medicines and [nationally completed name]').

Warnings and precautions
Talk to your doctor or pharmacist before taking [nationally completed name]

When should you contact your doctor?

<u>Seek urgent medical attention</u>

- if you notice possible signs of a blood clot that may mean you are suffering from a blood clot in the leg (i.e. deep vein thrombosis), a blood clot in the lung (i.e. pulmonary embolism), a heart attack or a stroke (see 'Blood clots' section below).

For a description of the symptoms of these serious side effects please go to "How to recognize a blood clot".

Tell your doctor if any of the following conditions apply to you.
If the condition develops, or gets worse while you are using[nationally completed name], you should also tell your doctor.

- In some situations you need to take special care while using [nationally completed name] or any other combination pill, and your doctor may need to examine you regularly.If you have Crohn's disease or ulcerative colitis (chronic inflammatory bowel disease);
- If you have haemolytic uremic syndrome (HUS - a disorder of blood clotting causing failure of the kidneys);
- If you have sickle cell anaemia (an inherited disease of the red blood cells);
- If you have elevated levels of fat in the blood (hypertriglyceridaemia) or a positive family history for this condition. Hypertriglyceridaemia has been associated with an increased risk of developing pancreatitis (inflammation of the pancreas);
- If you need an operation, or you are off your feet for a long time (see in section 2 'Blood clots');
- If you have just given birth you are at an increased risk of blood clots. You should ask your doctor how soon after delivery you can start taking[nationally completed name];
- If you have an inflammation in the veins under the skin (superficial thrombophlebitis);
- If you have had patches of discolouration on your face (chloasma) during pregnancy or when using another contraceptive pill. In this case, avoid direct exposure to the sun while you are using[nationally completed name];
- 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.

Do not hesitate to ask your doctor or pharmacist for advice if you have any doubts about the use of[nationally completed name].

BLOOD CLOTS
Using a combined hormonal contraceptive such as [nationally completed name] increases your risk of developing a blood clot compared with not using one. In rare cases a blood clot can block blood vessels and cause serious problems.
Blood clots can develop

- in veins (referred to as a 'venous thrombosis', 'venous thromboembolism' or VTE)
- in the arteries (referred to as an 'arterial thrombosis', 'arterial thromboembolism' or ATE).

Recovery from blood clots is not always complete. Rarely, there may be serious lasting effects or, very rarely, they may be fatal.

It is important to remember that the overall risk of a harmful blood clot due to [nationally completed name] **is small.**

HOW TO RECOGNICE A BLOOD CLOT
Seek urgent medical attention if you notice any of the following signs or symptoms.

Are you experiencing any of these signs?	What are you possibly suffering from?

• Swelling of one leg or along a vein in the leg or foot especially when accompanied by:
  • pain or tenderness in the leg which may be felt only when standing or walking
  • increased warmth in the affected leg
  • change in colour of the skin on the leg e.g. turning pale, red or blue
	Deep vein thrombosis

• Sudden unexplained breathlessness or rapid breathing; • Sudden cough without an obvious cause, which may bring up blood; • Sharp chest pain which may increase with deep breathing; • Severe light headedness or dizziness; • Rapid or irregular heartbeat • Severe pain in your stomach; If you are unsure, talk to a doctor as some of these symptoms such as coughing or being short of breath may be mistaken for a milder condition such as a respiratory tract infection (e.g. a 'common cold').	Pulmonary embolism
Symptoms most commonly occur in one eye: • Immediate loss of vision or • Painless blurring of vision which can progress to loss of vision	Retinal vein thrombosis (blood clot in the eye)
• Chest pain, discomfort, pressure, heaviness • Sensation of squeezing or fullness in the chest, arm or below the breastbone; • Fullness, indigestion or choking feeling; • Upper body discomfort radiating to the back, jaw, throat, arm and stomach; • Sweating, nausea, vomiting or dizziness; • Extreme weakness, anxiety, or shortness of breath; • Rapid or irregular heartbeats	Heart attack

• Sudden weakness or numbness of the face, arm or leg, especially on one side of the body; • Sudden confusion, trouble speaking or understanding; • Sudden trouble seeing in one or both eyes; • Sudden trouble walking, dizziness, loss of balance or coordination; • Sudden, severe or prolonged headache with no known cause; • Loss of consciousness or fainting with or without seizure. Sometimes the symptoms of stroke can be brief with an almost immediate and full recovery, but you should still seek urgent medical attention as you may be at risk of another stroke..	Stroke
• Swelling and slight blue discolouration of an extremity; • Severe pain in your stomach (acute abdomen)	Blood clots blocking other blood vessels

BLOOD CLOTS IN A VEIN

What can happen if a blood clot forms in a vein?
- The use of combined hormonal contraceptives has been connected with an increase in the risk of blood clots in the vein (venous thrombosis). However, these side effects are rare. Most frequently, they occur in the first year of use of a combined hormonal contraceptive.
- If a blood clot forms in a vein in the leg or foot it can cause a deep vein thrombosis (DVT).
- If a blood clot travels from the leg and lodges in the lung it can cause a pulmonary embolism.
- Very rarely a clot may form in a vein in another organ such as the eye (retinal vein thrombosis).

When is the risk of developing a blood clot in a vein highest?
The risk of developing a blood clot in a vein is highest during the first year of taking a combined hormonal contraceptive for the first time. The risk may also be higher if you restart taking a combined hormonal contraceptive (the same product or a different product) after a break of 4 weeks or more.
After the first year, the risk gets smaller but is always slightly higher than if you were not using a combined hormonal contraceptive.
When you stop [nationally completed name] your risk of a blood clot returns to normal within a few weeks.

What is the risk of developing a blood clot?
The risk depends on your natural risk of VTE and the type of combined hormonal contraceptive you are taking.

The overall risk of a blood clot in the leg or lung (DVT or PE) with [nationally completed name] is small.

- Out of 10,000 women who are not using any combined hormonal contraceptive and are not pregnant, about 2 will develop a blood clot in a year.
- Out of 10,000 women who are using a combined hormonal contraceptive that contains levonorgestrel, norethisterone, or norgestimate about 5-7 will develop a blood clot in a year.
- Out of 10,000 women who are using a combined hormonal contraceptive that contains gestodene such as [nationally completed name] between about 9 and 12 women will develop a blood clot in a year.
- The risk of having a blood clot will vary according to your personal medical history (see "Factors that increase your risk of a blood clot" below)

	Risk of developing a blood clot in a year
Women who are **not using** a combined hormonal tablet/patch/ring and are not pregnant	About 2 out of 10,000 women
Women using a combined hormonal contraceptive pill containing **levonorgestrel, norethisterone or norgestimate**	About 5-7 out of 10,000 women
Women using [nationally completed name]	About 9-12 out of 10,000 women

Factors that increase your risk of a blood clot in a vein

The risk of a blood clot with [nationally completed name] is small but some conditions will increase the risk.

Your risk is higher:

- If you are very overweight (body mass index or BMI over 30kg/m^2);
- If one of your immediate family has had a blood clot in the leg, lung or other organ at a young age (e.g. below the age of about 50). In this case you could have a hereditary blood clotting disorder;
- If you need to have an operation, or if you are off your feet for a long time because of an injury or illness, or you have your leg in a cast. The use of [nationally completed name] may need to be stopped several weeks before surgery or while you are less mobile. If you need to stop [nationally completed name] ask your doctor when you can start using it again.
- As you get older (particularly above about 35 years);
- If you gave birth less than a few weeks ago

The risk of developing a blood clot increases the more conditions you have.

Air travel (>4 hours) may temporarily increase your risk of a blood clot, particularly if you have some of the other factors listed.

It is important to tell your doctor if any of these conditions apply to you, even if you are unsure. Your doctor may decide that [nationally completed name] needs to be stopped.

If any of the above conditions change while you are using [nationally completed name], for example a close family member experiences a thrombosis for no known reason; or you gain a lot of weight, tell your doctor.

BLOOD CLOTS IN AN ARTERY
What can happen if a blood clot forms in an artery?
Like a blood clot in a vein, a clot in an artery can cause serious problems. For example, it can cause a heart attack or a stroke.

Factors that increase your risk of a blood clot in an artery
It is important to note that the risk of a heart attack or stroke from using [nationally completed name] is very small but can increase:
- With increasing age (beyond about 35 years);
- If you smoke. When using a combined hormonal contraceptive like [nationally completed name] you are advised to stop smoking. If you are unable to stop smoking and are older than 35 your doctor may advise you to use a different type of contraceptive;
- If you are overweight;
- If you have high blood pressure;
- If a member of your immediate family has had a heart attack or stroke at a young age (less then about 50). In this case you could also have a higher risk of having a heart attack or stroke;
- If you, or someone in your immediate family, have a high level of fat in the blood (cholesterol or triglycerides);
- If you get migraines, especially migraines with aura;
- If you have a problem with your heart (valve disorder, disturbance of the rhythm called atrial fibrillation);
- If you have diabetes.

If you have more than one of these conditions or if any of them are particularly severe the risk of developing a blood clot may be increased even more.

If any of the above conditions change while you are using[nationally completed name], for example you start smoking, a close family member experiences a thrombosis for no known reason; or you gain a lot of weight, tell your doctor.

[nationally completed name] and cancer
Breast cancer has been observed slightly more often in women using combination pills, but it is not known whether this is caused by the pill. It is possible that these women were simply examined more thoroughly and more frequently, meaning that the breast cancer was detected earlier.
In women using combination pills for a relatively long time, studies have reported cases of cervical cancer. It is currently unknown whether it is caused by the pill or connected with sexual behaviour and other factors such as an infection with the so called human papilloma virus.
The occurrence of breast tumours gradually decreases after stopping the combination hormonal

contraceptives. It is important to regularly check your breasts and you should contact your doctor if you feel any lump.

In rare cases, benign liver tumours, and in even fewer cases malignant liver tumors have been reported in pill users. Contact your doctor if you have unusually severe abdominal pain.

Psychiatric disorders
Some women using hormonal contraceptives including [nationally completed 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.

Bleeding between periods
During the first few months that you are taking [nationally completed name], you may have unexpected bleeding (bleeding outside the placebo days). 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 during the placebo days
If you have taken all the yellow active 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. Only start the next strip if you are sure that you are not pregnant.

Other medicines and [nationally completed name]

Talk to your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. Always tell your doctor which medicines or herbal products you are already using including any medicines obtained without a prescription. Also tell any other doctor or dentist who prescribes another medicine (or the pharmacist) that you use[nationally completed 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 have an influence on the blood levels of[nationally completed name], can make it **less effective in preventing pregnancy** and can cause unexpected bleeding.
These include:

- medicines used for the treatment of
  - epilepsy (e.g. primidone, phenytoin, barbiturates, carbamazepine, oxacarbazepine or topiramate, felbamate)
  - tuberculosis (e.g. rifampicin)
  - HIV and Hepatitis C Virus infections (so-called protease inhibitors and nonnucleoside reverse transcriptase inhibitors, such as ritonavir, nevirapine, efavirenz)
    - fungal infections (e.g. griseofulvin)

- arthritis, arthrosis (etoricoxib)high blood pressure in the blood vessels in the lungs (bosentan)
- the herbal remedy St. John's wort)
-

[nationally completed name] may **influence the effect** of other medicines, e.g.:
- cyclosporine
- the anti-epileptic lamotrigine (this could lead to an increased frequency of seizures)
- theophylline (used to treat breathing problems)
- tizanidine (used to treat muscle pain and/or muscle cramps).

Do not use [nationally completed name] if you have Hepatitis C and are taking the medicines 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 medicines.
[nationally completed name] can be restarted approximately 2 weeks after completion of this treatment. See section "Do not use [nationally completed name]".

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

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, you must not take [nationally completed name]. If you become pregnant while taking [nationally completed name] you must stop immediately and contact your doctor. If you want to become pregnant, you can stop taking [nationally completed name] at any time (see also "If you want to stop taking [nationally completed name]").

Breast-feeding
Use [nationally completed name] is generally not as advisable when a woman is breast-feeding. If you want to use the tablet while still nursing, it is best to contact your doctor.

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

Driving and using machines

The effect of ethinylestradiol/gestodene on the ability to drive or operate machinery has not been studied. [nationally completed name] is not likely to impact your ability to drive or operate machinery. Dizziness has been reported as a side-effect. If you experience dizziness do not drive or operate machinery until it has resolved.

[nationally completed name] contains lactose and soya lecithin
If you have been told by your doctor that you have intolerance to some sugars contact your doctor before taking this medicine. If you are allergic to peanut or soya do not take this medicine.

This medicine contains less than 1 mmol sodium per dose, that is to say essentially 'sodium-free'

3 How to take [nationally completed name]

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

When and how you should take [nationally completed name]
Each blister contains 24 active yellow tablets and 4 white placebo tablets.

The two differently colored tablets of [nationally completed name] are arranged in order. A strip contains 28 tablets.

Take one tablet of [nationally completed name] every day, with some water if needed, with or without food, but you should take them at approximately the same time every day.

Do not confuse the tablets: take a yellow tablet for the first 24 days, and then a white tablet for the last 4 days. Then you must start a new strip straight away (24 yellow and then 4 white tablets). There is therefore no gap between two strips.

Because of the different composition of the tablets it is necessary to begin with the first tablet on the upper left and that you take the tablets every day. For the correct order, follow the direction of the arrows on the strip.

Preparation of the strip
To help you keep track, there are 7 stickers each with 7 days of the week for each strip of[nationally completed name]. Choose the week sticker that starts with the day you begin taking the tablets. For example, if you start on a Wednesday, use the week sticker that starts with "WED".

Then stick the corresponding strip in the upper left hand corner of the pack, on the "Start" position. There is now a day indicated above every tablet and you can see whether you have taken a tablet. You should take the tablets in the order shown by the arrows.

During the 4 days when you are taking the white placebo tablets (the placebo days), bleeding should start (also called withdrawal bleeding). This usually starts on the 2nd or 3rd day after the last yellow active tablet of[nationally completed name]. Once you have taken the last white tablet you should start the next strip, even if you have not stopped bleeding. This means that you should start every strip on the same day of the week, and menstruation should occur during the same days of every month.

If you take [nationally completed name] as indicated, you are also protected against pregnancy during the 4 days you take the placebo tablets.

When can you start with the first strip?

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

Begin with [nationally completed name] on the first day of the cycle (that is, the first day of your period). If you start {Nationally completed 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 a combined hormonal contraceptive, or combined contraceptive vaginal ring or patch*

You can start [nationally completed name] preferably on the day after the last active tablet (the last tablet containing active substances) of your previous tablet, but at the latest on the day after the tablet- free days of your previous tablet finish (or after the last inactive tablet of your previous tablet). When changing from a combined contraceptive vaginal ring or patch, follow the advice of your doctor.

Changing from a progestogen-only-method (progestogen-only tablet, injection, implant or a progestogen-releasing IUD)

You may switch any day from the progestogen-only tablet (from an implant or an IUD on the day of its removal, from an injectable when the next injection would be due) but in all of these case 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

You can start [nationally completed name] between 21 and 28 days after having a baby. 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 [nationally completed name] use.

If, after having a baby, you have had sex before starting [nationally completed name] (again), you must first be sure that you are not pregnant or you must wait until your next period.

- If you are breast-feeding and want to start [nationally completed name] (again) after having a baby Read the section on "Breast-feeding".

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

If you take more [nationally completed name] than you should
In case of taking an overdose of yellow tablets you may possibly experience nausea, vomiting and withdrawal bleeding. Withdrawal bleeding may even occur in girls before their menarche, if they accidentally take this medicine.

If you forget to take [nationally completed name]

The last four tablets in the **4th** row of the strip are the placebo tablets. If you forget one of these tablets, this has no effect on the reliability of [nationally completed name]. Throw the forgotten placebo tablet.

If you miss a yellow, active tablet (tablets 1-24 of your blister-strip), you must do the following:

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

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

- **More than one tablet forgotten in this strip**: Contact your doctor.

- **One tablet forgotten between days 1 - 7 (first row)**

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 must realize that there is a risk of pregnancy. In that case, contact your doctor.

- **One tablet forgotten between days 8 - 14 (second row)**

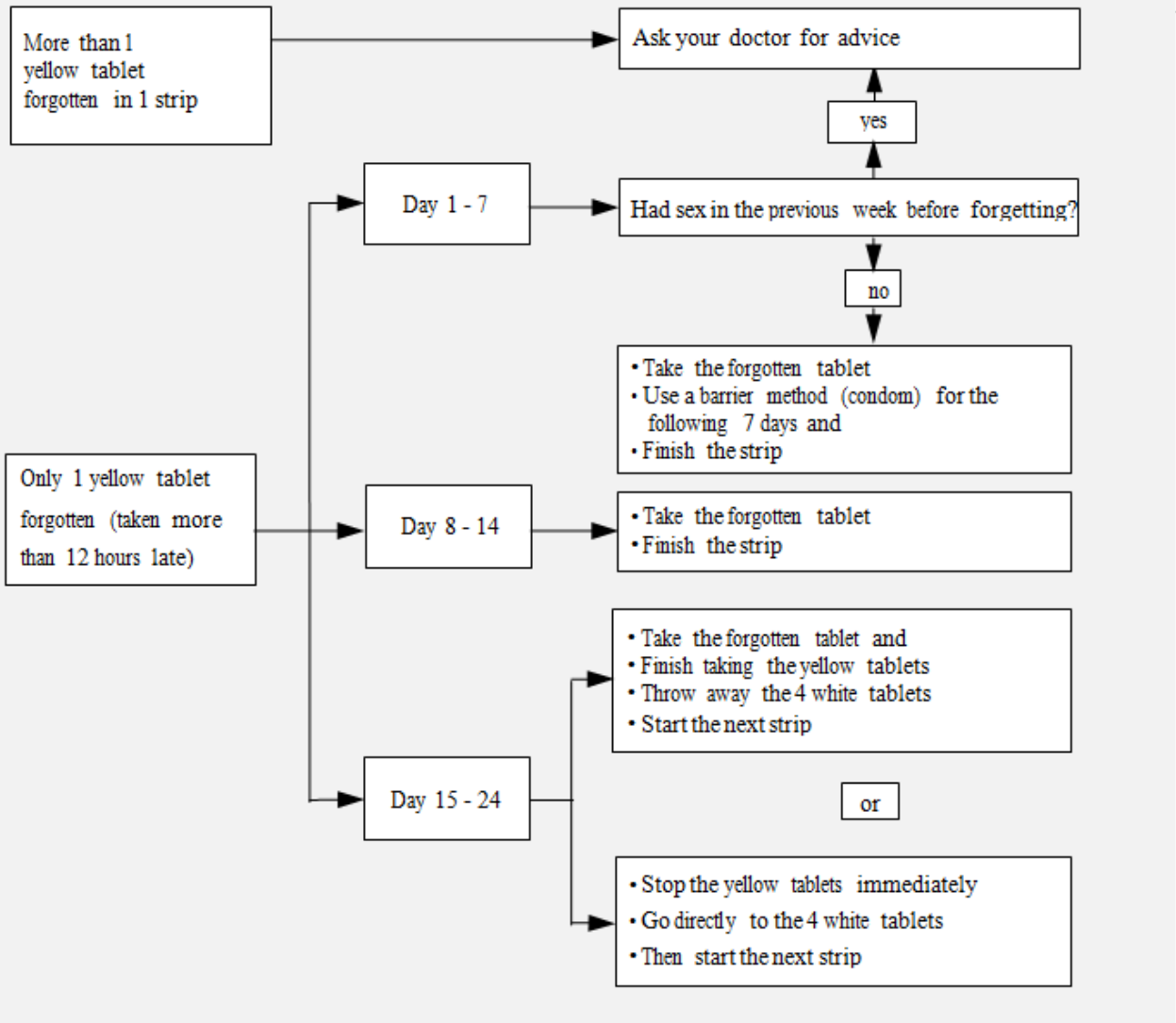
Take the forgotten tablet as soon as you remember, even if that means that you have to take two tablets at the same time. Continue taking the tablets at the usual time. The protection against pregnancy is not reduced, and you do not need to take extra precautions.

- **One tablet forgotten between days 15 - 24 (third or fourth row)**

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 white placebo tablets on this strip, throw them away, and start the next strip (the starting day will be different).
   Most likely, you will have a period at the end of the second strip - while taking the white placebo tablets - but you may have light or menstruation-like bleeding during the second strip.
2. You can also stop the active yellow tablets and go directly to the 4 white placebo tablets **(before taking the placebo tablets, record the day on which you forgot your tablet)**. If you want to start a new strip on the day you always start, take the placebo tablets for *less than 4 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 placebo days, this may mean that you are pregnant. Your must contact your doctor before you start the next strip.



What should you do in case of vomiting or bad diarrhoea
If you vomit or have bad diarrhoea within 3-4 hours after taking a yellow tablet, there is a chance that the active ingredients haven't been completely absorbed into the body. The situation is comparable to the situation in which a person forgot to take a tablet. Therefore, in the case of vomiting or having bad diarrhoea, you may take a yellow tablet from a reserve strip as soon as possible. If possible, take it within 12 hours of the usual time for your tablet intake. If this is not possible, or more than 12 hours have passed, follow the advice in the section "If you forget to take [nationally completed name]".

If this happens during several days, you should use an additional contraceptive method (for example, condom).

Delaying your period: what you need to know
Even if it is not recommended, you can delay your period by not taking the white placebo tablets from the 4th row and going straight to a new strip of [nationally completed name] and finishing it. You may experience light or menstruation-like bleeding while using this second strip. Finish this second strip by taking the 4 white tablets from the 4th row. Then start your 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 placebo days. If you have to change this day, reduce the number of placebo days – when you take the white placebo tablets – (but never increase them – 4 is the maximum!). For example, if you start taking the placebo tablets 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. You may not have any bleeding during this time. You may then experience light or menstruation-like bleeding.

If you are not sure what to do, consult your doctor.

If you want to stop taking [nationally completed name]
You can stop taking [nationally completed name] whenever you want. If you don't want to become pregnant, ask your doctor for advice regarding other reliable birth control methods.

If you stop because you want to become pregnant, generally it is recommended to wait until you have had a natural period before trying to get pregnant. You will then be able to calculate more easily when the delivery will take place.

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. If you get any side effect, particularly if severe and persistent, or have any change to your health that you think may be due to [nationally completed name], please talk to your doctor.

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”).

An increased risk of blood clots in your veins (venous thromboembolism [VTE]) or blood clots in your arteries (arterial thromboembolism [ATE]) is present for all women taking combined hormonal contraceptives. For more detailed information on the different risks from taking combined hormonal contraceptives please see section 2 “What you need to know before you use [nationally completed name]”.

Very common (may affect more than 1 in 10 people):
- headache, including migraine
- abdominal pain
- breast pain
- breast tenderness

Common (may affect up to 1 in 10 people)
- vaginal infection including vaginal thrush;
- spotting, bleeding between periods
- altered mood swings including depression or altered sexual appetite
- nervousness or dizziness
- nausea, vomiting
- feeling bloated
- acne
- painful periods
- change in blood flow during your period
- changes to vaginal discharge or change to the cervix (ectropion)
- absence of menstrual bleeding during the treatment or when it is halted
- water retention in tissue or oedema (severe fluid retention)
- weight loss or gain
- skin rash
- hair loss

Uncommon (may affect up to 1 in 100 people)
- increased appetite
- decreased appetite
- excessive growth of body hair
- discoloured patches on the face (chloasma)
- changes in laboratory test results: increase in cholesterol, triglyceride levels or increased blood pressure

- discharge from the nipple
- increased breast size
- worsening of varicose veins

Rare (may affect up to 1 in 1,000 people)
- pancreatic disorder
- harmful blood clots in a vein or artery for example:
  - in a leg or foot (i.e. DVT)
  - in a lung (i.e. PE)
  - heart attack
  - stroke
  - mini-stroke or temporary stroke-like symptoms, known as a transient ischaemic attack (TIA)
  - blood clots in the liver, stomach/intestine, kidneys or eye.

The chance of having a blood clot may be higher if you have any other conditions that increase this risk (See section 2 for more information on the conditions that increase risk for blood clots and the symptoms of a blood clot)
- liver or biliary disorders (such as hepatitis or abnormal function of the liver)
- gallbladder disease including gallstones or worsening of this condition
- decrease in serum folate levels

Not known: frequency cannot be estimated from the available data
- worsening of symptoms of hereditary and acquired angioedema;
- benign liver tumour (called focal nodular hyperplasia or hepatic adenoma) or malignant liver tumour;
- worsening of an immune system disease (lupus), of a liver disease (porphyria), or of a disease known as chorea characterized by irregular, sudden, involuntary movements;
- obstruction of the bile flow in the liver or worsening of this condition
- ischaemic bowel disease, possible aggravation of inflammatory bowel disease - symptoms include abdominal cramps and pain, diarrhoea (which may be bloody), weight loss.
- intolerance to a sugar called glucose
- contact lens intolerance
- abdominal cramps
- jaundice (yellowing of the skin or eyes)
- tender red lumps under the skin (erythema nodosum)
- inflammation of the optic nerve which can lead to partial or total loss of vision
- blood or urinary disorders (haemolytic and uremic syndrome);
- a type of skin reaction called erythema multiforme.

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

Reporting of side effects
If you get any side effects, talk to your doctor or pharmacist or nurse. This includes any possible side effects not listed in this leaflet.
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 [nationally completed name]

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the carton after "Do not use after:" or "EXP". The expiry date refers to the last day of that month.

This medicine does not require any special temperature storage conditions. Keep blister in the outer carton, in order to protect from light.

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 [nationally completed name] contains

The active substances are Gestodene and ethinyl estradiol.

The other excipients
[nationally completed name] has tablets of 2 colours:

- Each yellow tablet contains:
  Core: 0.060 mg of gestodene and 0.015 mg of ethinyl estradiol. The other ingredients (excipients) are lactose monohydrate, microcrystalline cellulose (E 460), polacrilin potassium, magnesium stearate (E 572)
  Coating: Polyvinyl alcohol (E 1203), titanium dioxide (E171), lecithin (soya) (E 322), talc (E 553b), yellow iron oxide (E 172), xanthan gum (E572).
- Each white tablet (inactive tablet or placebo tablet) contains only excipients (no active substances) which are lactose monohydrate, povidone K-25 (E 1201), sodium starch glycolate

(type A), colloidal anhydrous silica (E 551), anhydrous aluminium oxide, magnesium stearate (E 572).

What [nationally completed name] looks like and contents of the pack

- Each active film-coated tablet is a round, plain, yellow film-coated tablet.
- Each placebo tablet is a white, round, biconvex tablet.

[nationally completed name] is available in clear to slightly opaqutransparent strips (blisters) of 28 tablets: 24 yellow active tablets and 4 white placebo tablets.
Pack sizes are of 1, 3 or 6 strips, each strip with 28 tablets. Not all pack sizes may be marketed.

Houder van de vergunning voor het in de handel brengen en fabrikant
Vergunninghouder:
Sandoz B.V., Hospitaaldreef 29, 1315 RC Almere, Nederland

Fabrikanten:
Laboratorios León Farma, S.A.
C/ La Vallina s/n, Polígono Industrial
Navatejera, Villaquilambre, León, 24008
Spanje

LEK Pharmaceuticals d.d.
Verovškova ulica 57
1526 Ljubljana
Slovenië

Salutas Pharma GmbH
Otto-von-Guericke-Allee 1,
Barleben, Sachsen-Anhalt,
39179, Duitsland

In het register ingeschreven onder: RVG 116167

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

Nederland:	Kosidina 0,060 mg/0,015 mg, filmomhulde tabletten
Oostenrijk:	Kosidina 0,060 mg/0,015 mg – Filmtabletten
Tsjechië:	Tanielle 0,060 mg/0,015 mg
Estland:	Iamna
Hongarije:	Iamna 60 mikrogramm/15 mikrogram filmtabletta

Italië:	Dremisette
Letland:	Iamna 60/15 mikrogramu apvalkotās tabletes
Polen:	Revella
Portugal:	Kosidina
Roemenië:	Gestoden/etinilestradiol Sandoz 60 micrograme/15 micrograme comprimate filmate
Slovenië:	Gestoden/etinilestradiol Lek 60 mikrogramov/15 mikrogramov filmsko obložene tablete
Slowakije:	Tanielle 0,060 mg/0,015 mg

Deze bijsluiter is voor het laatst goedgekeurd in februari 2024.