Bijsluiter: Informatie voor de patiënt

Kosidina 0,075 mg/0,030 mg 21+7, 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 using 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, pharmacist or nurse.
- 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, pharmacist or nurse. 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 a contraceptive tablet and is used to prevent pregnancy.
- Each tablet contains a small amount of two different female hormones, namely ethinylestradiol and gestodene.
- Contraceptive tablets as [nationally completed name] that contain two hormones are called “combination” contraceptives.

[nationally completed name] needs to be taken as directed to prevent pregnancy.

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., 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 the body temperature and of the 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 have (or have ever had) a blood clot in a blood vessel of your legs (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 had 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 Ethinylestradiol or gestodene, or any of the other ingredients of this medicine listed in section 6. This can be recognised by itching, rash or swelling.

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 (see also in section "Other medicines and [nationally completed name]").

Warnings and precautions
Talk to your doctor or pharmacist before taking this medicine.

When should you contact your doctor?
Seek urgent medical attention
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 clot' (thrombosis) section below.
For a description of the symptoms of these serious side effects please go to "How to recognise 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.

- if you have Crohn's disease or ulcerative colitis (chronic inflammatory bowel disease);
- if you have systemic lupus erythematosus (SLE –; a disease affecting your natural defence system);
- if you have haemolytic uraemic 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 varicose veins.
- if a close relative has (had) breast cancer or breast cancer was diagnosed
- if you have a disease of the liver or the gallbladder
- if you have diabetes
- if you have depression
- if you have epilepsy (see section "Other medicines and [nationally completed name]")
- 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 (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.

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 RECOGNISE 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: o pain or tenderness in the leg which may be felt only when standing or walking o increased warmth in the affected leg o 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 pill/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/m2);
- 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.

Ethinylestradiol/gestodene and cancer
Breast cancer has been observed slightly more often in women using combined contraceptives, 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 contraceptives 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 tumours, and in even fewer cases malignant liver tumours have been reported in contraceptives users. This can cause internal bleeding leading to severe pain in the abdomen.
Contact your doctor if you have unusual severe abdominal pain. You may need to stop taking [nationally completed name].
Cervical cancer has been reported to occur more often in women using contraceptives for a long time. This finding may not be caused by the contraceptives, but may be related to sexual behaviour and other factors

Bleeding between periods
During the first few months that you are taking [nationally completed name], you may have unexpected bleeding (bleeding outside the gap week). If this bleeding continues longer than a few months, or if it begins after some months, your doctor must investigate the cause.

What you must do if no bleeding occurs in the gap week
If you have taken all the tablets correctly, have not had vomiting or severe diarrhoea and you have not taken any other medicines, it is highly unlikely that you are pregnant.
If the expected bleeding does not happen twice in succession, you may be pregnant. Contact your doctor immediately. Do not start the next strip until you are sure that you are not pregnant.

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.

Use in children
[nationally completed name] is not intended for use in females whose periods have not yet started.

Other medicines and [nationally completed name]
Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.
Always tell the doctor, who prescribes [nationally completed 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 [nationally completed name]. They can tell you if you need to take additional contraceptive precautions (for example condoms) and if so, for how long, or, whether the use of another medicine you need must be changed.

- Some medicines can have an influence on the blood levels of [nationally completed name] and can make it **less effective in preventing pregnancy**, or can cause unexpected bleeding.

These include
- medicines used for the treatment of
  - epilepsy (e.g. topiramate, felbamate, primidone, phenytoin, barbiturates, carbamazepine, oxcarbamazepine),

  - tuberculosis (e.g. rifampicin),
  - high blood pressure in the blood vessels in the lungs (bosentan),
  - HIV and Hepatitis C Virus infections (so-called protease inhibitors and non-nucleoside reverse transcriptase inhibitors, such as ritonavir, nevirapin, efavirenz)
  - fungal infectious diseases (e.g. ketoconazole, griseofulvin),
  - arthritis, arthrosis (etoricoxib)
- the herbal remedy St. John's wort.

If you want to use herbal products containing St. John's wort while you are already using [nationally completed name] you should consult your doctor first.

- [nationally completed name] may influence the efficacy of other medicines, e.g.:
  - medicines containing cyclosporine (medicine against infections),
  - 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]".

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

Pregnancy and breast-feeding
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 you doctor.
Use of [nationally completed name] 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
There is no information suggesting that use of [nationally completed name] affects driving or use of machines.

[nationally completed 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.

3. How to take [nationally completed name]

Each strip contains 21 white active tablets and 7 green placebo tablets.
The two differently coloured tablets of [nationally completed name] are arranged in order. A strip contains 28 tablets.
Take one tablet of [nationally completed name] every day, if necessary with a small amount of water. You may take the tablets with or without food, but should take the tablets every day at approximately the same time.

Do not confuse the tablets: take a white tablet for the first 21 days and then a green tablet for the last 7 days. You must then start a new pack straightaway (21 white and then 7 green tablets). There is therefore no gap between packs.
Because of the different composition of the tablets it is necessary to begin with the first table 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 labels each with the 7 days of the week for each strip of [nationally completed name]. Choose the week label that starts with the day you begin taking the tablets. For example, if you start on a Wednesday, use the week label that starts with "WED".
Stick the week label along the top of the [nationally completed name] strip where it reads "Place the label here" so that the first day is above the first white tablet at the upper left of the strip.
There is now a day indicated above every tablet and you can see whether you have taken a certain tablet. The arrows show the order you are to take the tablets.
During the 7 days when you are taking the green placebo tablets (the placebo days), bleeding should begin (so-called withdrawal bleeding). This usually starts on the 2nd or 3rd day after the last white active tablet of [nationally completed name]. Once you have taken the last green tablet, you should start with the following strip, whether your bleeding has stopped or not. This means that you should start every strip on the same day of the week, and that the withdrawal bleed should occur on the same days each month.
If you use [nationally completed name] in this manner, you are protected against pregnancy also during the 7 days when you are taking a placebo tablet.
Always take [nationally completed name] exactly as described in this leaflet or as your doctor has told you. Check with your doctor or pharmacist if you are not sure

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 menstruation). 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 another combined hormonal contraceptive, or combined contraceptive vaginal *ring or patch.*

You can start [nationally completed name] on the day after taking the last tablet containing the active substance of your previous "pill", but at the latest the day after the placebo tablet period of your previous contraceptive 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 preparation containing only a progestogen (progestogen-only pill, injection, implant or a progestogen-releasing IUD).
You may switch any day from an injectable when the next injection would be due from the progestogen-only pill and from an implant or the IUD on the day of its removal.) 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 with [nationally completed 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 [nationally completed name] use.

If, after having a baby, you have had intercourse before starting [nationally completed name] (again), you must first be sure that you are not pregnant otherwise you must wait until the next menstrual bleed.

Ask your doctor for advice in case you are not sure when to start taking [nationally completed name]

If you are breastfeeding and want to start taking [nationally completed name] (again) after having a baby.
[nationally completed name] should not be used during breast feeding. Read the section 2 on "Pregnancy and breast feeding".

If you take more [nationally completed name] than you should
There are no reports of serious harmful results of taking too many [nationally completed name] tablets.
If you take several tablets at once then you may have symptoms of nausea, dizziness, abdominal pain, drowsiness/fatigue or vomiting. Young girls may have bleeding from the vagina.
If you have taken too many [nationally completed name] tablets, or you discover that a child has taken some, ask your doctor or pharmacist for advice.

If you forget to take [nationally completed name]

- If you are **less than 12 hours** late taking a tablet, the protection from 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 from pregnancy may be reduced. The greater the number of tablets that you have forgotten, the greater is the risk that the protection from pregnancy is reduced.

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

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

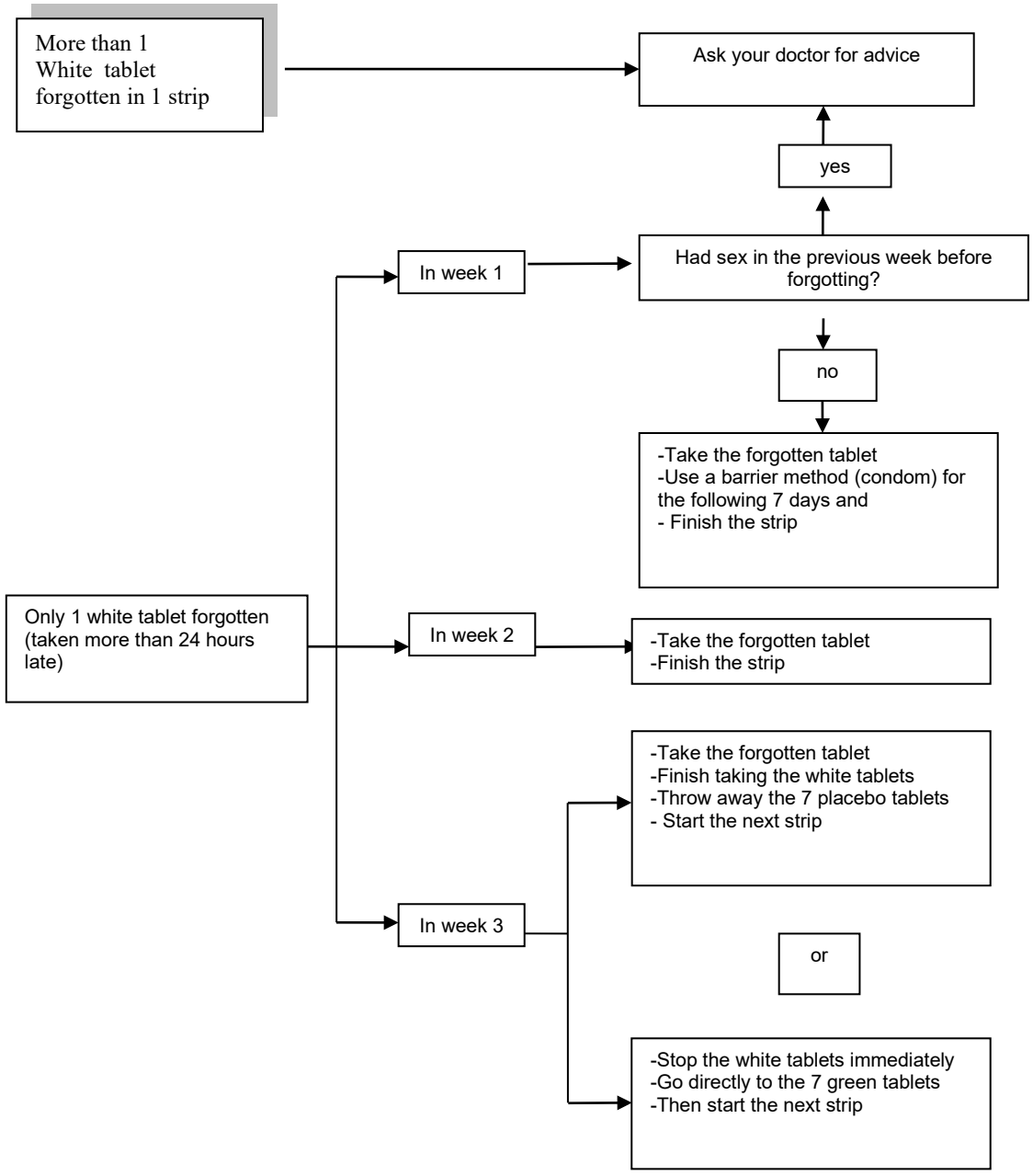
If you forgot one tablet in week 1
Take the forgotten tablet as soon as you remember, even if that means that you have to take two tablets at the same time. Take the tablets again at the usual time and use **extra precautions** for the next 7 days, for example, a condom. If you have had intercourse in the week before the oversight or you have forgotten to start a new strip after the placebo tablet period, you must realize 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, and you do not need to take extra precautions.

If you forgot one tablet in week 3
You can choose between two possibilities:
1. Take the forgotten tablet as soon as you remember, even if that means that you have to take two tablets at the same time. Take the tablets again at the usual time. Instead of the placebo-tablet 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 placebo-tablet 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 placebo-tablet 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 placebo-tablet period, this may mean that you are pregnant. You must contact your doctor before you go on to the next strip.



What you must do in the case of gastro-intestinal disturbances
In case of severe gastro-intestinal disturbances (e.g., vomiting or diarrhoea), absorption may not be complete and additional contraceptive measures should be taken. If you vomit within 3-4 hours of taking a tablet or you have severe diarrhoea, 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 [nationally completed name]".

Delay of menstrual period: what you must know
Even if not recommended, delay of your menstrual period (withdrawal bleed) is possible. This can be done by going straight on to a new strip of [nationally completed name] instead of the placebo-tablet period, after the first strip. You may experience spotting (drops or flecks of blood) or breakthrough bleeding while using this second strip. After the usual placebo-tablet 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 placebo-tablet period. If you have to change this day, you do this by making the placebo-tablet period shorter **(but never longer than 7 days!**). For example, if your placebo-tablet 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 placebo-tablet period very short (for example, for 3 days or less) then it may be that you do not have any bleeding during this placebo-tablet period. You may then experience spotting (droplets or flecks or blood) or breakthrough bleeding.

If you are not sure how to proceed, contact your doctor for advice. If you stop taking [nationally completed name]
You can stop taking [nationally completed 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 have any further questions on the use of this product, 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.
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]".

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").

Other possible side effects

Very common (may affect more than one in 10 people)
- headache including migraines,
- spotting and intermenstrual bleeding.

Common (may affect up to 1 in 10 women):
- vaginal infection including vaginal thrush,
- altered mood swings including depression or altered sexual appetite,,
- nervousness, movement disorders,
- visual disturbances,
- nausea, vomiting, abdominal pain,
- acne,
- breast problems such as pain, tenderness, swelling or secretion,
- painful periods or change in blood flow during your period,
- vaginal discharge changes or cervix changes (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,

Bleeding and spotting between your periods can sometimes occur for the first few months but this usually stops once your body has adjusted to [nationally completed name]. If it continues, becomes heavy or starts again, contact your doctor.
- irritability

Uncommon (may affect up to 1 in 100 women):
- excess of lipids in blood,
- changed appetite,
- abdominal cramps or wind,
- skin rash, excessive growth of body hair, hair loss or discoloured patches on the face (chloasma),
- hypertension.

Rare (may affect up to 1 in 1,000 women):
- signs of a severe allergic reaction: swelling of the hands, face, lips, mouth, tongue or throat. A swollen tongue/throat may lead to difficulty swallowing and breathing, a red bumpy rash (hives) and itching
- increased blood glucose level (glucose intolerance),
- irritation of the eyes if you wear contact lenses,
- middle ear disorders,
- cholestatic jaundice (abnormal bile flow in the liver causing yellowing of the skin),
- 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)

- decrease of a vitamin in the blood (folate),
- erythema nodosum,

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

- hepatocellular carcinomas (cancer of the liver),
- worsening of a certain disease of the immune system (systemic lupus erythematosus),
- worsening of the metabolic disease porphyria affecting blood pigments,
- worsening of St. Vitus dance (Sydenham's chorea),
- visual disorders such as blurred vision, loss of vision (optic neuritis),
- enlarged and tortuous veins (varicose veins),
- disorders of the pancreas,
- inflammation of the large intestine due to inadequate blood supply (ischemic colitis),
- increased risk of biliary calculi,
- increased risk of bile stasis,
- skin reddening with formation of blisters and nodules (erythema multiforme),
- specific blood disorder that causes kidney damage (haemolytic-uraemic syndrome).

Not known: frequency cannot be estimated from the available data

- inflammation of the intestine (Inflammatory bowel disease),
- liver problems (inflammation or abnormal function).
- worsening of symptoms of hereditary and acquired angioedema

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 <To be completed nationally>. 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 strip and carton after "EXP". The expiry date refers to the last day of that month.

Do not store above 30°C. Keep the strip 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
Each box of [nationally completed name] contains 28 tablets, with a set of self-adhesive strips showing the days of the week. The pack sizes are 1x28, 3x28 and 6x28 tablets

Each strip of {nationally completed name contains 21 white active tablets containing 0.075 mg (equivalent to 75 micrograms) gestodene, and 0.030 mg (equivalent to 30 micrograms) ethinylestradiol, and 7 green placebo tablets, which are inactive.
Each active white tablet also contains the inactive ingredients: lactose monohydrate (59.12 mg), microcrystalline cellulose, povidone K-30, magnesium stearate and polacrilin potassium.

Each placebo green tablet contains lactose monohydrate (55.5 mg), maize starch, povidone K-30, silica colloidal anhydrous, magnesium stearate, hypromellose 2910, triacetin (E 1518), polysorbate 80, titanium dioxide (E 171), FD&C blue 2 aluminium lake (E 132) and yellow iron oxide (E 172).

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

Active tablets: Round, white tablets, with a diameter of 5.7 mm approximately. The white tablet is debossed with a '*C'* on one side and '*33'* on the other side.

Placebo tablets: Round, green film-coated tablets, with a diameter of 5 mm approximately.

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

Vergunninghouder
Sandoz B.V., Hospitaaldreef 29, 1315 RC Almere, Nederland

Fabrikant
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 116281

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

Nederland:	Kosidina 0,075 mg/0,030 mg 21+7, tabletten
Tsjechië:	Tanielle 0,075 mg/0,030 mg
Finland:	Kosidina 3 mikrog/75 mikrog
Polen:	Revella
Roemenië:	Gestoden/Etinilestradiol Sandoz 75 micrograme/30 micrograme comprimate
Slovenië:	Gestoden/etinilestradiol Sandoz 0,075 mg/0,03 mg tablete
Slowakije:	Gestodene/Etinylestradiol Sandoz 0,075 mg/0,030 mg

Deze bijsluiter is voor het laatst goedgekeurd in februari 2024.