

## BIJSLUITER: INFORMATIE VOOR DE GEBRUIKER

### Ethinylestradiol/Desogestrel 0,02 mg/0,15 mg Teva, tabletten

desogestrel/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 <Product name> is and what it is used for
2. What you need to know before you take <Product name>
3. How to take <Product name>
4. Possible side effects
5. How to store <Product name>
6. Contents of the pack and other information

#### 1. What <Product name> is and what it is used for

##### Composition and type of pill

<Product name> tablet is a combined oral contraceptive pill, also called the combined pill. Each tablet contains a small amount of two types of female hormones, namely, a progestogen, desogestrel and an oestrogen, ethinylestradiol. Because of the small amount of hormones, <Product name> is considered a low-dose contraceptive. Because both hormones are combined in the same quantity in all tablets in the strip, it is called a single-phase combination pill.

##### What is this medicine used for?

These help to stop you from getting pregnant, just as your natural hormones would stop you conceiving again when you are already pregnant.

The combined contraceptive pill protects you against getting pregnant in three ways. These hormones

1. stop the ovary from releasing an egg each month (ovulation).
2. also thicken the fluid (at the neck of the womb making it more difficult for the sperm to reach the egg).
3. alter the lining of the womb to make it less likely to accept a fertilised egg.

## 2. What you need to know before you take *<Product name>*

### General notes

Before you start using *<Product 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 *<Product 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 *<Product name>*, or where the reliability of the pill may be decreased. In such situations you should either not have sex, 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 *<Product name>* alters the monthly changes of body temperature and of cervical mucus.

***<Product name>*, like other hormonal contraceptives, does not protect against HIV infection (AIDS) or any other sexually transmitted diseases (STDs).**

### Do not take *<Product name>*

You should not use *<Product 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 ever had) an inflammation of the pancreas (pancreatitis)
- if you have (or have ever had) a liver disease and your liver function is still not normal.
- if you have (or have ever had) a tumour in the liver.
- if you have (or have ever had) or if you are suspected to having breast cancer or cancer of the genital organs.
- if you have any unexplained bleeding from the vagina.
- if you have an overgrowth of the lining of the uterus (womb)
- if you are pregnant or might be pregnant
- if you are allergic to ethinylestradiol or desogestrel, or any of the other ingredients of this medicine (listed in section 6)
- if you have hepatitis C and are taking the medicinal products containing ombitasvir/paritaprevir/ritonavir and dasabuvir, glecaprevir/pibrentasvir or sofosbuvir/velpatasvir/voxilaprevir (see also in section “Other medicines and <Product name>”).

If any of these situations occur while you are already using use <Product name> you must stop using it immediately and contact your doctor. In the meantime, use another non-hormonal method of contraception. See also 'General notes' at the beginning of section 2.

### Warnings and precautions

Talk to your doctor or pharmacist before taking <Product name>.

In some situations you need to take special care while using <Product name> or any other combination pill, and your doctor may need to examine you regularly.

#### **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 clots’ 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 <Product name>, you should also tell your doctor.

- if you smoke
- if you have diabetes
- if you are overweight
- if you have high blood pressure
- if you have a disease of the heart valves or a specific heart rhythm disorder
- if you have an inflammation in the veins under the skin (superficial thrombophlebitis)
- if you have varicose veins
- if someone in your immediate family has had a thrombosis, a heart attack or a stroke
- if you suffer from migraines
- 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 *<Product name>*;
- if a close relative has or has ever had breast cancer
- if you have a disease of the liver or the gallbladder
- if you have depression
- if you have epilepsy (see “Other medicines and *<Product name>*”)
- if you have a disease that first appeared during pregnancy or earlier use of sex hormones (for example, hearing loss, a blood disease called porphyria, skin rash with blisters during pregnancy (gestational herpes) a nerve disease causing sudden movements of the body (Sydenham’s chorea)
- if you have or have ever had chloasma (a discoloration of the skin especially of the face or neck known as “pregnancy patches”). If so, avoid direct 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

### **The pill and blood clots (thrombosis)**

#### **BLOOD CLOTS**

Using a combined hormonal contraceptive such as *<Product 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 *<Product 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:	Deep vein thrombosis

<ul style="list-style-type: none"> <li>• pain or tenderness in the leg which may be felt only when standing or walking</li> <li>• increased warmth in the affected leg</li> <li>• change in colour of the skin on the leg e.g. turning pale, red or blue</li> </ul>	
<ul style="list-style-type: none"> <li>• sudden unexplained breathlessness or rapid breathing;</li> <li>• sudden cough without an obvious cause, which may bring up blood;</li> <li>• sharp chest pain which may increase with deep breathing;</li> <li>• severe light headedness or dizziness;</li> <li>• rapid or irregular heartbeat</li> <li>• severe pain in your stomach;</li> </ul> <p>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’).</p>	Pulmonary embolism
<p>Symptoms most commonly occur in one eye:</p> <ul style="list-style-type: none"> <li>• immediate loss of vision or</li> <li>• painless blurring of vision which can progress to loss of vision</li> </ul>	Retinal vein thrombosis (blood clot in the eye)
<ul style="list-style-type: none"> <li>• chest pain, discomfort, pressure, heaviness</li> <li>• sensation of squeezing or fullness in the chest, arm or below the breastbone;</li> <li>• fullness, indigestion or choking feeling;</li> <li>• upper body discomfort radiating to the back, jaw, throat, arm and stomach;</li> <li>• sweating, nausea, vomiting or dizziness;</li> <li>• extreme weakness, anxiety, or shortness of breath;</li> <li>• rapid or irregular heartbeats</li> </ul>	Heart attack
<ul style="list-style-type: none"> <li>• sudden weakness or numbness of the face, arm or leg, especially on one side of the body;</li> <li>• sudden confusion, trouble speaking or understanding;</li> <li>• sudden trouble seeing in one or both eyes;</li> <li>• sudden trouble walking, dizziness, loss of balance or coordination;</li> <li>• sudden, severe or prolonged headache with no known cause;</li> <li>• loss of consciousness or fainting with or without seizure.</li> </ul>	Stroke

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.	
<ul style="list-style-type: none"> <li>• swelling and slight blue discoloration of an extremity;</li> <li>• severe pain in your stomach (acute abdomen)</li> </ul>	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 <Product 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 <Product 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 desogestrel such as <Product 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 <b>not using</b> 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 <b>levonorgestrel, norethisterone or norgestimate</b>	About 5-7 out of 10,000 women
Women using <Product 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 <Product 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 30 kg/m<sup>2</sup>);
- 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 <Product name> may need to be stopped several weeks before surgery or while you are less mobile. If you need to stop <Product 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 <Product name> needs to be stopped.

If any of the above conditions change while you are using <Product 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 <Product name> is very small but can increase:

- with increasing age (beyond about 35 years);
- **if you smoke.** When using a combined hormonal contraceptive like <Product 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 than 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 *<Product 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.

### **The pill 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 treatment. For example it may be that more tumours are detected in women on combination 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 women taking the pill over a longer period of time, there are more frequent cases of cervical cancer. The most important risk factor for this is an existing infection with a certain virus (HPV). The increased risk may be likewise associated with sexual behaviour (e.g. frequent change in partners) and other factors (such as not using another non-hormonal method of contraception (e.g. a condom)).

In rare cases, benign liver tumours, and in even fewer cases malignant liver tumours have been reported in pill users. Sometimes these tumours have led to life-threatening internal bleeding. If you suddenly experience severe abdominal pain, you should contact your doctor immediately.

### **Bleeding between periods**

During the first few months that you are taking *<Product name>*, you may have unexpected bleeding (bleeding outside the tablet-free period). If this bleeding occurs for more than a few months, or if it begins after some months, your doctor must find out what is wrong.

### **What you must do if no bleeding occurs in the tablet-free period**

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 *<Product 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.

### **Children and adolescents**

No clinical data on efficacy and safety are available in adolescents under 18 years of age.

### **Other medicines and *<Product name>***



Always tell the doctor which medicines or herbal products you are already using. Also tell any other doctor or dentist who prescribes another medicine (or the pharmacist) that you use *<Product name>*. They can tell you if you need to take additional non-hormonal contraceptive precautions (for example condoms) and if so, for how long.

Some medicines can

- affect the blood levels of *<Product name>*
- can make *<Product name>* less effective in preventing pregnancy
- may cause unexpected bleeding.

These include medicines used for the treatment of

- epilepsy (e.g. primidone, hydantoin, barbiturates, carbamazepine, oxcarbazepine, topiramate, felbamate)
- tuberculosis (e.g. rifampicin, rifabutin)
- HIV infections (e.g. ritonavir, nelfinavir, nevirapine, efavirenz)
- other infections (e.g. griseofulvin)
- pulmonary hypertension (bosentan)
- excessive sleepiness/ narcolepsy (modafinil)
- depressive mood (the herbal remedy St. John's wort (*Hypericum perforatum*))

If you are using medicines or herbal remedies that can make *<Product name>* less effective, you should also use a barrier method of contraception. Because the effect of another medicine on *<Product name>* may last up to 28 days after stopping that medicine, you should continue to use that additional barrier method of contraception during that time.

*<Product name>* may influence the effect of other medicines, e.g.

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

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

*<Product name>* can be restarted approximately 2 weeks after completion of this treatment. See section "Do not use *<Product name>*".

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

#### ***<Product name>* with food and drink**

*<Product name>* may be taken with or without food, if necessary with a small amount of water.

#### **Laboratory tests**

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

#### **Pregnancy and breast-feeding**

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

#### Pregnancy

Do not take <Product name> if you are pregnant or think you might be pregnant. If you become pregnant while taking <Product name> stop immediately and contact your doctor. If you want to become pregnant, you can stop taking the pill at any time.

#### Breast-feeding

The use of <Product 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 <Product name> affects driving or use of machines.

#### <Product name> contains lactose.

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before you take this medicinal product.

#### When should you see a doctor while taking this medicine?

##### **Regular check-ups**

Your doctor may advise you to make an appointment for regular pill check-ups. It depends on your personal situation how often you have to come back for a check-up and which examination takes place at that time.

##### **Contact the doctor as soon as possible in the following cases**

- if you notice any symptoms that may indicate a blood clot. This may mean that you have a blood clot in a blood vessel of the leg (deep vein thrombosis), a blood clot in a blood vessel of the lung (pulmonary embolism), a heart attack or stroke (see section “The Pill and blood clots (thrombosis)” above). For the description of the symptoms of these serious side effects, see “How to recognise a blood clot”.
- if there are any changes in your health (or that of your close relatives) related to any of the points mentioned elsewhere in this leaflet (see the sections on “When not to take this medicine” and “When to be extra careful with this medicine”)
- if you notice a lump in your breast
- if you experience symptoms of angioedema such as swollen face, tongue and/or throat and/or difficulty in swallowing or hives with difficulty in breathing
- when you start taking other medicines, in particular antibiotics (see section “Other medicines and <Product name>”)
- at least four weeks before you are due to undergo an operation or if you are bedridden or unable to walk for some time
- if you have a persistent or worsening loss of blood of an irregular nature
- if you have missed tablets in the first week of the strip and had sex in the seven days before the missed tablets
- if you have severe diarrhoea
- if the expected bleeding has not occurred for the second time in a row (do not start the new strip until your doctor says you can).

### 3. How to take <Product 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 to take the tablets**

Take one tablet of <Product name> every day, if necessary with a small amount of water. You may take the tablets with or without food, but you should take the tablets every day around the same time.

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

Then take no tablets for 7 days. In the course of these 7 tablet-free days (otherwise called a stop or gap week) bleeding should begin. This is so-called “withdrawal bleeding” usually starts on the 2<sup>nd</sup> or 3<sup>rd</sup> day after the last tablet of <Product name>.

On the 8<sup>th</sup> day after the last tablet of <Product name> (that is, after the 7-day tablet-free period), 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 <Product name> in this manner, you are also protected against pregnancy during the 7 days when 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 <Product name> on the first day of the cycle (that is the first day of your period). If you start <Product name> on the first day of your period 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 pill, or combination contraceptive vaginal ring or patch*  
You can start taking <Product name> preferably on the day after the last active tablet (the last tablet containing active substances) of your previous pill, but at the latest on the day after the tablet-free days of your previous pill (or after the last inactive tablet of your previous pill).

If you are switching from a vaginal ring or contraceptive patch, you can start using <Product name> on the day the ring or the last patch was removed. You may also start later, but you must start using <Product name> at the latest seven days after the removal of the ring or the last patch.

In addition, when you have used the pill, patch or ring completely according to the instructions and you are certain that you are not pregnant, you can stop taking the pill or remove the ring or patch on any day of your current cycle and switch to using <Product name> immediately.

If you follow these instructions it is not necessary to use any additional contraception (e.g. a condom).

- *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 an IUD on the day of its removal, from an injectable when the next injection would be due) but in all of these cases 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*  
If you have just given birth, your doctor will probably advise you to wait until your first spontaneous period, but sometimes it is possible to start earlier. Follow your doctor's advice. You can start <Product name> between 21 and 28 days after having a baby. If you start later than day 28, use a so-called barrier method (for example, a condom) during the first seven days of <Product name> use. If, after having a baby, you have had sex before starting <Product name> (again), be sure that you are not pregnant or wait until your next period.
- *If you are breast-feeding and want to start <Product name> (again) after having a baby.*  
Follow your doctor's advice. Read the section on "Breast-feeding".

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

### **If you take more <Product name> than you should**

There are no reports of serious harmful results of taking too many <Product name>. If you take several tablets at once then you may have symptoms of nausea or vomiting. Young girls may have bleeding from the vagina. If you have taken too many <Product name> tablets, or you discover that a child has taken some, ask your doctor or pharmacist for advice.

### **What to do if you forget to take <Product name>**

- 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 tablet at the beginning or the end of the strip. Therefore, you should keep to the following rules (see the diagram below):

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

- **One tablet forgotten in week 1**

Take the forgotten tablet as soon as you remember, even if that means that you have to take two tablets at the same time. 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 may be pregnant. In that case, contact your doctor.

- **One tablet forgotten in week 2**

Take the forgotten tablet as soon as you remember, even if that means that you have to take two tablets at the same time. 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 in week 3**

You can choose between two possibilities without having to use additional contraceptives:

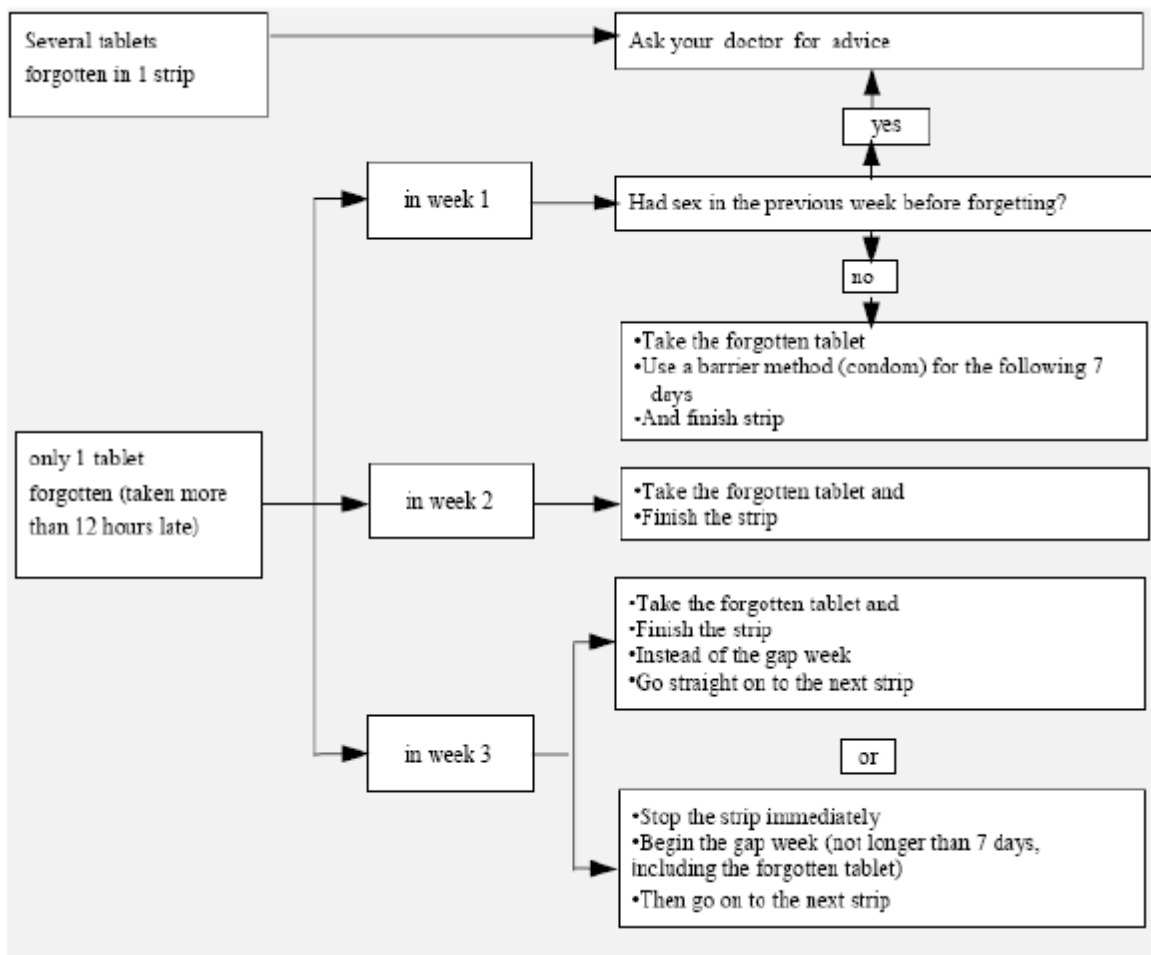
1. Take the forgotten tablet as soon as you remember, even if that means that you have to take two tablets at the same time. Continue taking the tablets at the usual time. Instead of taking the tablet-free period start next strip.

Most likely, you will have a period at the end of the second strip but you may also have light or menstruation-like bleeding during the second strip.

2. You can also stop taking 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 the day you always start, make the tablet-free period *less than 7 days*. If you follow this method, you can always start a new strip on your regular starting day.

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 bleeding in the first tablet-free period, you may be pregnant. Contact your doctor before you start the next strip.



### What to 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 almost the same as forgetting a tablet. After vomiting or diarrhoea, take another tablet from a reserve strip as soon as possible. If possible take it within 12 hours of when you normally take your pill. If this is not possible or 12 hours have passed, you should follow the advice given under “If you forget to take <Product name>”. If you have severe diarrhoea, please consult your doctor.

### Delay of menstrual period: what you need to know

Even though it is not recommended, you can delay your menstrual period by going straight to a new strip of Desogestrel 150 microgram and Ethinylestradiol 20 microgram tablets instead of the tablet-free period, and finishing it. You may experience light or menstruation-like bleeding while using this second strip. After the usual tablet-free period of 7 days, start the next strip.

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

### Changing 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 on about the same day. If you want to change this day, you can do so by shortening (but never by extending) the normal tablet-free period between two strips. For example, if your tablet-free days normally begin

on a Friday, and you want to change this to a Tuesday (3 days earlier) start a new strip 3 days earlier than usual. If you make the tablet-free interval very short (for example, 3 days or less) you may not have any bleeding during these days. You may then experience light or menstruation-like bleeding.

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

#### **In case of unexpected bleeding**

With all contraceptive pills, unexpected loss of blood (spotting or breakthrough bleeding) may occur in the first few months. You may not be able to manage without a sanitary towel or tampon. In any case, just keep taking your tablets. The irregular bleeding usually stops once your body has got used to the pill in question (after about 3 strips). If it lasts longer, gets worse or starts again, you should contact your doctor.

#### **If the expected bleeding does not occur**

If you have taken all the tablets correctly, have not had any vomiting or diarrhoea, and have not taken any other medicines, it is highly unlikely that you are pregnant. You can then safely continue with the next strip.

However, if the expected bleeding does not occur twice in a row, you may be pregnant. Contact your doctor immediately. Do not continue with the next *<Product name>* strip until your doctor has determined that you are not pregnant.

#### **If you want to stop taking *<Product name>***

You can stop taking *<Product 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 *<Product name>* and wait for a period before trying to become pregnant. You will be able to calculate the expected delivery date more easily.

#### Adolescents

No clinical data on efficacy and safety are available in adolescents below 18 years.

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 *<Product 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 *<Product name>*”.

#### **Serious reactions**

More serious reactions associated with combined hormonal contraceptive pills are detailed above in section 2 under “The pill and venous and arterial blood clots (thrombosis)” and “The pill and cancer”. Please read these subsections carefully, and if you have any questions, ask your doctor.

Contact a doctor immediately and stop taking <Product name>, 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”).

As with all combined pills, your menstrual pattern may change, especially during the first few months of use. This difference may be in how often you have a bleed (absence of bleeding, less often, more often or continuously), how heavy the bleeding is, or how long the bleeding lasts.

*The following serious side effects have been reported in women using the pill:* Crohn's disease or ulcerative colitis (chronic inflammatory bowel diseases), systemic lupus erythematosus (SLE, a disease of the connective tissue), epilepsy, the rash known as herpes gestationis, chorea (a movement disease), a blood disorder called haemolytic uraemic syndrome - HUS (a disorder where blood clots cause the kidneys to fail), brown patches on the face and body (chloasma), movement disorder called Sydenham's chorea, yellowing of the skin, gynaecological disorders (endometriosis, uterine myoma).

### **Other possible side effects**

The following side effects have been reported in women using the pill, which can occur in the first few months after starting <Product name>, but they usually stop once your body has adjusted to the pill. The most commonly reported side effects (*may affect up to 1 in 10 users*) are irregular bleeding and weight gain.

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

depressed mood, mood altered, headache, nausea, abdominal pain, tender breasts, breast pain, irregular bleeding, weight increased.

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

fluid retention, decreased sexual desire, nervousness, migraine, dizziness, high blood pressure, vomiting, diarrhoea, acne, rash, nettle-rash (urticaria), none or reduced bleeding, bleeding between the expected periods, breast enlargement.

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

vaginal candidiasis (fungal infection), hypersensitivity, increased sexual desire, eye irritation due to contact lens, impaired hearing (otosclerosis), 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). Loss of hair (alopecia), itching, skin disorders (erythema nodosum – a skin disease associated with joint pain, fever, hypersensitivity, or infection, and characterized by small, painful, pink to blue nodules under the skin and on the shins that tend to recur; erythema multiforme – a skin disease characterized by solid raised spots on the skin or fluid-filled blisters lesions and reddening or discoloration of the skin often in concentric zones about the lesions), vaginal discharge, breast discharge, weight decreased.

### **Before you have any blood tests**



Tell your doctor or the laboratory staff that you are taking the pill, because oral contraceptives can affect the results of some tests.

### **Reporting of side effects**

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the 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 <Product name>**

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

This medicinal product does not require any special temperature storage conditions. Store in original package in order to protect from moisture and light.

Do not use this medicine after the expiry date which is stated on the package 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 <Product name> contains**

- The active substances are: desogestrel and ethinylestradiol.  
Each tablet contains 150 micrograms desogestrel and 20 micrograms ethinylestradiol.
- The other ingredients are:  
All-rac-alpha-tocopherol, potato starch, povidone K30 (E1201), stearic acid (E570), silica, colloidal anhydrous (E551) and lactose.

### **What <Product name> looks like and contents of the pack**

Each tablet is round, white to off-white, uncoated, biconvex, debossed with ‘141’ on one side and other side plain.

Each clear transparent PVC/PVDC-Aluminium strip of <Product name> contains 21 white tablets.

Each box of <Product name> contains 1, 3, 6 or 13 strips of 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  
Nederland

*Fabrikant*  
Merckle GmbH  
Ludwig-Merckle-Str. 3  
89143 Blaubeuren  
Duitsland

**In het register ingeschreven onder**  
RVG 112197

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

Denemarken	Denise
Nederland	Ethinylestradiol/Desogestrel 0,02/0,15 mg Teva, tabletten

Deze bijsluiter is voor het laatst goedgekeurd in december 2023.