

Package leaflet: information for the user
Yasmin, filmcoated tablets, 0.03 mg/3 mg

ethinylestradiol/drospirenone

Read the entire 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.

Do you have any questions? Contact your doctor or pharmacist.

Do not pass this medicine on to others, as it has been prescribed only for you. It may be harmful to others.

Do you experience any side effects listed in section 4? Or do you experience a side effect not listed in this leaflet? Then contact your doctor or pharmacist.

Important things to know about combined hormonal contraceptives:

These medicines are one of the most reliable reversible contraceptive methods when used correctly.

They slightly increase the risk of developing a blood clot (thrombosis) in the veins and arteries, especially in the first year of using a combined hormonal contraceptive or if you restart after a break of 4 weeks or longer.

Be alert and contact your doctor if you think you may have symptoms of a blood clot (see section 2 'Blood clots (thrombosis)').

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1. What is Yasmin and what is this medicine used for?

Yasmin is a contraceptive pill and is used to prevent pregnancy.

Each film-coated tablet contains a small amount of two different female hormones, namely drospirenone and ethinylestradiol.

Contraceptive pills that contain two hormones are called 'combination pills'.

2. When should you not use this medicine or be extra careful with it?

General remarks

Before you start using this medicine, read the information about blood clots (thrombosis) in section 2. It is especially important that you read what the symptoms of a blood clot are – see section 2 'Blood clots (thrombosis)'.

Before you can start using this medicine, your doctor will ask you some questions about your personal medical history and that of your close family members. The doctor will also measure your blood pressure and, depending on your personal situation, may also conduct other tests.

This leaflet describes various situations in which you should stop using this medicine or in which its reliability may be reduced. In those situations, you should either not have sex or use an additional non-hormonal contraceptive, such as a condom or another barrier method. Do not use the temperature method or periodic abstinence. These methods can be unreliable because this medicine affects the monthly changes in body temperature and cervical mucus.

Like other hormonal contraceptives, this medicine does not protect against infection with the HIV virus (AIDS) or other sexually transmitted diseases (STDs).

When should you not use this medicine?

You should not use this medicine if you have any of the diseases listed below. If you have one or more of the diseases listed below, tell your doctor. Your doctor will discuss with you which other form of contraception is more suitable for you.

Do not use this medicine:

if you have a blood clot in a blood vessel of the legs (deep vein thrombosis, DVT), the lungs (pulmonary embolism, PE) or another organ, or have had this in the past

if you know you have a disorder affecting your blood clotting – for example, protein C deficiency, protein S deficiency, antithrombin III deficiency, factor V Leiden, or antibodies against phospholipids

if you need to undergo surgery or are unable to walk for a long period of time (see section 'Blood clots (thrombosis)')

if you have ever had a heart attack or stroke

if you have angina pectoris (a condition causing severe chest pain and can be an early sign of a heart attack) or a transient ischemic attack (TIA – temporary symptoms of a stroke), or have ever had this

if you have any of the following diseases, which increase the risk of a blood clot in your arteries:

- o severe diabetes with blood vessel damage
- o severely high blood pressure
- o a severely high level of fat in your blood (cholesterol or triglycerides)
- o a condition called hyperhomocysteinemia

if you have a type of migraine called 'migraine with aura', or have ever had this

if you have (or have ever had) liver disease and your liver function is still not normal

if your kidneys are not functioning properly (kidney failure)

if you have (or have ever had) a liver tumor

if you have (or have ever had) breast cancer or cancer of the genital organs, or if it is suspected that you have it

if you have unexplained vaginal bleeding

if you are allergic to any of the ingredients in this medicine. You can find these ingredients in section 6 of this leaflet. This can cause itching, rash, or swelling.

Do not use Yasmin if you have hepatitis C and are taking medicines containing ombitasvir/paritaprevir/ritonavir and dasabuvir, glecaprevir/pibrentasvir or sofosbuvir/velpatasvir/voxilaprevir (see also section 2 'Are you taking any other medicines?').

More information about special patient groups

Children and adolescents

This medicine is not intended for women who have not yet started menstruating.

Older women

Yasmin is not intended for use after menopause.

Women with liver disease

Do not take this medicine if you have liver disease. See also 'When should you not use this medicine?' and 'When should you be extra careful with this medicine?'

Women with kidney disease

Do not use this medicine if your kidneys are not functioning well or in case of acute kidney failure. See also 'When should you not use this medicine?' and 'When should you be extra careful with this medicine?'

When should you be extra careful with this medicine?

When should you contact your doctor? Seek emergency medical help

- if you notice possible complaints or symptoms of a blood clot, which may indicate that you have a blood clot in your leg (i.e., deep vein thrombosis), a blood clot in your lung (i.e., pulmonary embolism), a heart attack, or a stroke (see the section 'Blood clots (thrombosis)' below).

For a description of the complaints or symptoms of these serious side effects, go to 'How to recognize a blood clot?'

Tell your doctor if any of the following situations apply to you.

Contact your doctor before using this medicine. In some situations, you need to be extra careful when using this medicine or another combination pill. It may be necessary for you to be regularly monitored by your doctor. If the condition develops or worsens while using this medicine, you should also inform your doctor.

If someone in your immediate family has or has ever had breast cancer

If you have a liver or gallbladder disease

If you have diabetes

If you have depression (severe despondency)

If you have Crohn's disease or ulcerative colitis (chronic inflammatory bowel disease)

If you have hemolytic uremic syndrome (HUS - a blood clotting disorder that causes kidney failure)

If you have sickle cell anemia (a hereditary disease of the red blood cells)

If you have elevated fat levels in your blood (hypertriglyceridemia), or if this condition runs in your family or has occurred in your family. Hypertriglyceridemia has been associated with a higher risk of developing pancreatitis (an inflammation of the pancreas)

If you need to undergo surgery or are immobilized for a long period (see 'Blood clots (thrombosis)' in section 2)

If you have recently given birth, you have an increased risk of developing blood clots.

Ask your doctor how soon after delivery you can start using this medication

If you have an inflammation in the veins just under the skin (superficial thrombophlebitis)

If you have varicose veins

If you have epilepsy (see 'Are you using any other medications?', page 10)

If you have systemic lupus erythematosus (SLE - a disease that affects your natural immune system)

If you have a disease that first appeared during pregnancy or with previous use of sex hormones (for example, hearing loss, a blood disease called porphyria, skin rash with blisters during pregnancy (herpes gestationis), a nerve disease with sudden body movements (Sydenham's chorea))

If you have or have ever had chloasma (a yellow-brown discoloration of the skin, especially of the face or neck, so-called 'pregnancy spots'). In that case, avoid direct sunlight or ultraviolet light.

If you experience symptoms of angioedema, such as a swollen face, tongue and/or throat and/or difficulty swallowing or hives possibly with breathing problems, contact your doctor immediately. Products containing estrogen hormones may cause or worsen symptoms of hereditary and acquired angioedema.

BLOOD CLOTS (THROMBOSIS)

If you use a combined hormonal contraceptive like Yasmin, you have a higher risk of developing blood clots than if you do not use a combined hormonal contraceptive. In rare cases, a blood clot can block a blood vessel and cause serious problems.

Blood clots can form

in veins (this is called 'venous thrombosis', 'venous thromboembolism' or VTE),
in arteries (this is called 'arterial thrombosis', 'arterial thromboembolism' or ATE).

One does not always fully recover from blood clots. In rare cases, there can be long-term serious effects, or in very rare cases, blood clots can be fatal.

It is important for you to know that the overall risk of a harmful blood clot from this medication is small.

HOW TO RECOGNIZE A BLOOD CLOT?

Seek emergency medical help if you notice any of the following complaints or symptoms.

Do you experience any of these complaints or symptoms? from?	What might you suffer
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swelling of a leg or along a vein in a leg or foot, especially if accompanied by: pain or tenderness in the leg, which you may only feel when standing or walking increased temperature in the affected leg discoloration of the skin of the leg, for example, becoming pale, red, or blue	Deep vein thrombosis
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sudden unexplained shortness of breath or rapid breathing sudden coughing without a clear cause, where you may cough up blood sharp chest pain, which may worsen when you take a deep breath severe lightheadedness or dizziness • rapid or irregular heartbeat severe pain in your stomach.	Pulmonary embolism
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If in doubt, contact a doctor, as some of these symptoms, such as coughing or shortness of breath, may mistakenly be considered a milder illness, such as a respiratory infection (e.g., a cold).

Symptoms usually occur in one eye: sudden loss of vision, or painless blurred vision, which may develop into loss of vision
Venous thrombosis in the retina (blood clot in the eye)

pain, discomfort, pressure or heavy feeling on the chest tight or full feeling in the chest, arm or under the breastbone
full feeling, indigestion or shortness of breath discomfort in the upper body radiating to the back, jaw, throat, arm and stomach
sweating, nausea, vomiting or dizziness
extreme weakness, anxiety or shortness of breath
rapid or irregular heartbeat
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 without known cause
reduced consciousness or fainting with or without epileptic seizure.
Stroke

The symptoms of a stroke can sometimes last only briefly and recover almost immediately and completely. Nevertheless, you should still seek emergency medical help, because you may be at risk of having another stroke.

swelling and slight bluish discoloration of an arm or leg
severe pain in your abdomen (acute abdomen)
Blood clots that other block 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 associated with a higher risk of blood clots in a vein (venous thrombosis). However, these side effects are rare. They usually occur in the first year of using a combined hormonal contraceptive.

If a blood clot forms in a vein in a leg or foot, it can cause a deep vein thrombosis (DVT).

If a blood clot is carried from the leg and lodges in the lung, it can cause a pulmonary embolism.

It is very rare for a blood clot to form in a vein in another organ, such as the eye (retinal venous thrombosis).

When is the risk of a blood clot in a vein highest?

The risk of blood clots in a vein is highest in the first year a woman first uses a combined hormonal contraceptive. The risk may also be increased if you restart using a combined hormonal contraceptive (the same product, or a different product than before) after a break of 4 weeks or more.

After the first year, the risk decreases, but it remains slightly higher than if you do not use a combined hormonal contraceptive.

If you stop taking this medicine, your risk of a blood clot returns to normal within a few weeks.

How high is the risk of a blood clot?

The risk depends on your natural risk of VTE, and the type of combined hormonal contraceptive you are using.

The overall risk of a blood clot in a leg or lung (deep vein thrombosis or pulmonary embolism) with this medicine is small.

- Out of every 10,000 women who do not use any combined hormonal contraceptive and are not pregnant, about 2 will develop a blood clot in a year.
- Out of every 10,000 women who use a combined hormonal contraceptive containing levonorgestrel, norethisterone, or norgestimate, about 5-7 will develop a blood clot in a year.
- Out of every 10,000 women who use a combined hormonal contraceptive containing drospirenone, such as Yasmin, about 9 to 12 will develop a blood clot in a year.
- The risk of developing a blood clot depends on your personal medical history (see sections 'Factors that increase your risk of a blood clot in a vein/artery' below).

Risk of developing a blood clot in a year

Women who do not use a combined hormonal pill use and are not pregnant	About 2 out of every 10,000 women
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Women who use a combination pill that levonorgestrel, norethisterone, or norgestimate	About 5-7 out of every 10,000 women
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contains

Women who use Yasmin

About 9-12 out of every
10,000 women

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

The risk of a blood clot with this medication is small, but there are certain conditions that increase the risk. Your risk is higher:

if you are severely overweight (BMI [body mass index] over 30 kg/m²)
if one of your close relatives has had a blood clot in a leg, lung, or other organ at a young age (e.g., before the age of 50). In that case, you may have a hereditary clotting disorder. if you need to undergo surgery, or if you are immobile for a long time due to an injury or illness, or if your leg is in a cast. It may be necessary to stop using this medication a few weeks before surgery or when you are less mobile. If you need to stop this medication, ask your doctor when you can start using it again. if you are getting older (particularly over about 35 years)
if you have given birth in the past few weeks.

The risk of a blood clot increases as more of these conditions apply to you.

A plane trip (longer than 4 hours) can temporarily increase your risk of a blood clot, especially if some of the other mentioned conditions apply to you.

It is important to tell your doctor if one or more of these conditions apply to you, even if you are unsure. Your doctor may decide that you should stop using this medication.

If any of the above conditions change while you are using this medication, for example, if a close relative develops a blood clot (thrombosis) without a known cause, or if you gain a lot of weight, inform your doctor.

BLOOD CLOT IN AN ARTERY

What can happen if a blood clot forms in an artery?

BLOOD CLOT IN AN ARTERY

What can happen if a blood clot forms in an artery?

Just like a blood clot in a vein, a blood 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 for you to know that the risk of a heart attack or stroke from using this medication is very small, but it can increase:

with increasing age (above about 35 years)

if you smoke. If you use a combined hormonal contraceptive like Yasmin, it is advised that you stop smoking. If you cannot stop smoking and are over 35 years old, 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 (before the age of 50)^e year). In that case, you may also have an increased risk of having a heart attack or stroke.

if you, or a member of your immediate family, have high levels of fat in the blood (cholesterol or triglycerides)

if you suffer from migraines, especially migraines with aura

if you have heart disease (heart valve disease, or a heart rhythm disorder called atrial fibrillation)

if you have diabetes.

If more than one of these conditions applies to you, or if one of these diseases is particularly severe, the risk of getting a blood clot may be even further increased.

If any of the above conditions change while you are using this medication, for example, if you start smoking or if an immediate family member develops a blood clot (thrombosis) without a known cause, or if you gain a lot of weight, inform your doctor.

This medication and cancer

In women who use the combination pill, breast cancer is detected slightly more often, but it is not known if this is caused by pill use. For example, it may also be that more breast cancer is detected in women who use the combination pill because they are examined more frequently by their doctor. The occurrence of breast cancer gradually decreases after stopping the combination pill. It is important to regularly check your breasts. If you feel a lump, you should contact your doctor.

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

Psychiatric disorders

Some women using hormonal contraceptives, including Yasmin, have reported depression or low mood. Depression can be severe and may sometimes lead to suicidal thoughts. If you experience mood changes and symptoms of depression, contact your doctor as soon as possible for further medical advice.

Intermenstrual bleeding

During the first few months of using this medication, you may experience unexpected bleeding (bleeding outside the pill-free week). If this bleeding persists for more than a few months, or if it starts after a few months, your doctor should investigate what is happening.

What to do if you do not have a bleeding during the pill-free week

If you have taken all the tablets correctly, have not vomited, have not had severe diarrhea, and have not used other medications, it is very unlikely that you are pregnant.

If the expected bleeding does not occur twice in a row, you may be pregnant. Contact your doctor immediately. Do not start the next pack until you are sure you are not pregnant.

Are you using any other medications?

Always tell your doctor which medications and herbal remedies you are already using. Also inform any other doctor or dentist who prescribes you another medication (or the pharmacist) that you are taking this medication. They can tell you if it is necessary to take extra contraceptive measures (such as condoms) and, if so, how long you need to do this and whether the use of other medications you need should be adjusted.

Some medications

- can affect the blood levels of Yasmin
- can reduce the protection against pregnancy
- can cause unexpected bleeding.

These include:

medications for the treatment of

- o epilepsy (for example, primidone, phenytoin, barbiturates, carbamazepine, oxcarbazepine)
- o tuberculosis (for example, rifampicin)
- o infections with the HIV and hepatitis C virus (so-called protease inhibitors and non-nucleoside reverse transcriptase inhibitors such as ritonavir, nevirapine, efavirenz)
- o fungal infections (e.g., griseofulvin, ketoconazole) arthritis, osteoarthritis (etoricoxib)
- o high blood pressure
- o in the pulmonary blood vessels (bosentan) the herbal remedy St. John's wort.

Yasmin can affect the action of other medicines, for example

medicines containing cyclosporine

the anti-epileptic drug lamotrigine (this can lead to an increased number of seizures) theophylline (used in the treatment of respiratory problems) tizanidine (used in the treatment of muscle pain and/or muscle spasms).

Do not use Yasmin if you have hepatitis C and are taking medicines containing ombitasvir/paritaprevir/ritonavir and dasabuvir, glecaprevir/pibrentasvir or

sofosbuvir/velpatasvir/voxilaprevir as this can cause increased liver function values in the blood

(elevated ALT liver enzyme). Your doctor will prescribe another contraceptive before you start treatment with these medicines. Yasmin can be resumed approximately 2 weeks after the end of this treatment. See section 2 "When should you not use this medicine?".

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

What should you pay attention to with food and drink?

This medicine can be taken with or without food, if necessary with a little water.

Laboratory tests

Laboratory tests

If you need to have a blood test, tell your doctor or the laboratory staff that you are using the pill. Hormonal contraceptives can influence the results of some tests.

Pregnancy and breastfeeding

Do not use this medicine if you are pregnant. If you become pregnant while using this medicine, stop immediately and contact your doctor. If you want to become pregnant, you can stop using this medicine at any time (see 'If you stop using this medicine', page 15).

The use of this medicine is generally not recommended if a woman is breastfeeding. If you want to use the pill while breastfeeding, you should contact your doctor.

Are you pregnant, do you think you might be pregnant, do you want to become pregnant, or are you breastfeeding? Then contact your doctor or pharmacist.

Driving and using machines

There is no information indicating that this medicine affects driving or the use of machines.

Yasmin contains lactose

If you are intolerant to certain sugars, you should contact your doctor before using this medicine.

3. How to use this medicine?

Take 1 tablet every day, if necessary with a little water. You may take the tablets with or without food, but you should take the tablets at around the same time every day.

The strip contains 21 film-coated tablets. Each tablet is marked with the day of the week it should be taken. For example, if you start on a Wednesday, take a tablet marked 'Wed'. Follow the direction of the arrow on the strip until all 21 tablets have been taken.

Then do not take a tablet for 7 days. During these 7 pill-free days (also called a break week or pause week), a bleeding should start. This so-called 'withdrawal bleeding' usually begins on the second or third day of the break week.

On the eighth day after the last tablet (after the seven-day break week), you should start the next strip, regardless of whether your bleeding has stopped or not. This means that you start each strip on the same day of the week and that the withdrawal bleeding occurs on the same days each month.

If you use this medicine in this way, you are also protected against pregnancy during the 7 days that you do not take a tablet.

When can you start the first strip?

You have not used a hormonal contraceptive in the past month
Start this medicine on the first day of the cycle (this is the first day of your period). If you start this medicine on the first day of your period, you are immediately protected against pregnancy. You may also start on days 2-5 of the cycle, but then you must use an additional contraceptive (e.g., a condom) for the first 7 days.

Switching from a combined hormonal contraceptive, combined vaginal ring, or contraceptive patch

It is best to start this medication on the day after the last active tablet (the last tablet with active ingredients) of your previous pill, but no later than 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 combined vaginal contraceptive ring or contraceptive patch, you should follow your doctor's advice.

Switching from a progestogen-only contraceptive method (progestogen-only pill, injection, implant, or progestogen-releasing IUD) Switching from a progestogen-only pill can be done any day (for an implant or IUD on the day it is removed; for the injection on the day you would have the next injection) but in all cases use an additional contraceptive method (e.g., a condom) for the first 7 days of pill use.

After a miscarriage or abortion

Follow your doctor's advice.

After childbirth

If you have given birth, you can start this medication 21 to 28 days after delivery. If you start after day 28, use a so-called barrier method (e.g., a condom) for the first 7 days of using this medication.

If you have had sex after childbirth before starting (again) with this medication, you must be sure that you are not pregnant or wait until your next period.

If you are breastfeeding and want to start (again) with this medication after childbirth, read the chapter 'Breastfeeding', page 11.

Ask your doctor what to do if you are unsure when you can start.

Have you taken too much of this medication?

No reports have been made of serious harmful effects from taking too many tablets.

If you have taken multiple tablets at once, you may experience nausea, vomiting, or vaginal bleeding. Even girls who have not yet menstruated may experience vaginal bleeding if they accidentally take this medication.

If you have taken too many tablets, or if you discover that a child has taken multiple tablets, ask your doctor or pharmacist for advice.

Have you forgotten to take this medication?

If you are less than 12 hours late in taking a tablet, the protection against pregnancy is not reduced. Take the tablet as soon as you remember and take the next tablets at the usual time.

If you are more than 12 hours late in taking a tablet, the protection against pregnancy may be reduced. The more tablets you forget, the greater the risk of pregnancy.

The risk of insufficient protection against pregnancy is greatest if you forget a tablet at the beginning or end of the strip. Therefore, you must follow the following rules (see also the diagram on page 14):

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 it means taking two tablets at the same time. Take the next tablets at the usual time and use an additional contraceptive method, such as a condom, for the next 7 days. If you had sex in the week before the forgotten tablet, you may be pregnant. In this case, contact your doctor.

One tablet forgotten in week 2

Take the forgotten tablet as soon as you remember, even if it means taking two tablets at the same time. Take the next tablets at the usual time. The protection against pregnancy is not reduced, and you do not need to use additional contraceptive methods.

One tablet forgotten in week 3

You can choose between two options:

1. Take the forgotten tablet as soon as you remember, even if it means taking two tablets at the same time. Take the next tablets at the usual time. Then skip the tablet-free period and start the next strip immediately.
You will likely have bleeding at the end of the second strip, but you may also experience light or menstruation-like bleeding during the second strip.
2. You can also stop the strip and immediately take a 7-day tablet-free period (count the day you forgot the tablet). If you want to start on the day you always start a new strip, you must make your tablet-free period shorter than 7 days.

If you follow one of these two recommendations, you will remain protected against pregnancy.

If you forgot one of the tablets in a strip and you do not have bleeding during the next tablet-free period, you may be pregnant. Contact your doctor before starting the next strip.

What to do in case of vomiting or severe diarrhea

If you vomit or have severe diarrhea within 3-4 hours after taking a tablet, there is a chance that the active ingredients of the pill are not fully absorbed into the body. This situation is almost the same as forgetting a tablet. After vomiting or diarrhea, take a second tablet from a reserve strip as soon as possible. If possible, take it within 12 hours of the time you normally take your pill. If this is not possible, or if the 12 hours have already passed, you must follow the advice given under "Forgot to take this medicine?", page 13.

Postponing your bleeding: what you need to know

It is possible to postpone your bleeding, although it is not recommended. Postponement is possible by immediately continuing with a new strip of this medicine instead of a tablet-free period, and using it completely. During the use of the second strip, you may experience light or menstruation-like bleeding. Continue with the next strip after a regular 7-day tablet-free period.

You could ask your doctor for advice before deciding to delay your menstruation.

Changing the start day of your bleeding: what you need to know

If you take the tablets as directed, your bleeding will start during the tablet-free week. If you need to change the start day of your bleeding, reduce the number of tablet-free days (but never make it more than – 7 is the maximum number of days!). For example, if your tablet-free days normally start on a Friday and you want to shift them to a Tuesday (three days earlier), you must start a new strip three days earlier than usual. If you make the tablet-free interval very short (for example, three days or less), it is possible that you will not have bleeding during these days. In that case, you may experience light or menstruation-like bleeding.

If you are unsure how to do this, ask your doctor for advice.

If you stop using this medicine

You can stop using this medicine at any time. If you do not want to become pregnant, you can ask your doctor for advice on other reliable contraceptives. If you want to become pregnant, stop using this medicine and wait until you have a period before trying to conceive. This will make it easier to calculate the expected due date.

Do you have any other questions about using this medicine? Then contact your doctor or pharmacist.

4. Possible side effects

Like any medicine, this medicine can cause side effects. Not everyone experiences them. Do you experience a side effect, especially if it is severe and persistent, or does a change occur in your health condition that you think may be caused by this medicine? Then contact your doctor.

All women using combined hormonal contraceptives have a higher risk of blood clots in the veins (venous thromboembolism [VTE]) or blood clots in the arteries (arterial thromboembolism [ATE]). For more information on the different risks of using combined hormonal contraceptives, see section 2 'When should you not use this medicine or be extra careful with it?'

Serious side effect

Contact your doctor immediately if you experience symptoms of angioedema such as a swollen face, tongue and/or throat and/or difficulty swallowing or hives possibly together with breathing problems (see also section 2: 'When should you be extra careful with this medicine?').

Below is a list of side effects associated with the use of this medicine.

Common side effects (occur in less than 1 in 10 users):

- menstrual disorders, bleeding and blood loss outside the break week, breast pain, tender breasts
- headache, depression
- migraine
- nausea
- thick white discharge from the vagina and yeast infections in the vagina.

Sometimes occurring side effects (occur in less than 1 in 100 users):

- enlargement of the breasts, changed libido
- increased blood pressure, decreased blood pressure
- vomiting, diarrhea
- acne, eczema, itching, hair loss (alopecia)
- inflammations in the vagina
- fluid retention and changes in body weight

Rare side effects (occur in less than 1 in 1000 users):

- allergic reactions (hypersensitivity), asthma
- nipple discharge
- reduced hearing acuity
- the skin diseases erythema nodosum (characterized by painful bluish-red skin nodules) and erythema multiforme (characterized by a rash with circular redness or blisters)
- harmful blood clots in a vein or artery, for example:
 - o in a leg or foot (i.e., deep vein thrombosis)
 - o in a lung (i.e., pulmonary embolism)

- o heart attack
- o stroke
- o 'mini-stroke' or temporary symptoms similar to a stroke, known as TIA (transient ischemic attack)
- o blood clots in the liver, stomach/intestines, kidneys, or eyes.

The risk of developing a blood clot is higher if other conditions apply to you that increase this risk (see section 2 for more information on the conditions that increase the risk of blood clots and the symptoms of a blood clot).

Reporting side effects

If you experience side effects, contact your doctor or pharmacist. This also applies to possible side effects not listed in this leaflet. You can also report side effects directly via the Netherlands Pharmacovigilance Centre Lareb, website www.lareb.nl. By reporting side effects, you can help us obtain more information about the safety of this medicine.

5. How should you store this medicine?

Keep out of the sight and reach of children.

Store below 30°C. Keep in the original strip to protect from moisture.

Do not use this medicine after the expiry date. You can find it on the packaging after 'EXP:'. It states a month and a year. The last day of that month is the expiry date.

Do not flush medicines down the sink or toilet and do not throw them in the trash. Ask your pharmacist what to do with medicines you no longer use. Proper disposal of medicines ensures they are destroyed correctly and do not enter the environment.

6. Contents of the package and other information

What substances are in this medicine?

The active substances in this medicine are drospirenone and ethinylestradiol. Each tablet contains 3 milligrams of drospirenone and 0.030 milligrams of ethinylestradiol.

The other substances in this medicine are lactose monohydrate, corn starch, pregelatinized corn starch, povidone K25, magnesium stearate (E470b), hypromellose (E464), macrogol 6000, talc (E553b), titanium dioxide (E171) and yellow iron oxide (E172), see section 2 "Yasmin contains lactose".

What does Yasmin look like and what is in a package?

Each strip contains 21 light yellow film-coated tablets.

The tablets are film-coated tablets; the core of the tablet is coated. The tablets are light yellow, round with biconvex sides, one side of which is embossed with the letters 'DO' in a regular hexagon.

Yasmin is available in packages of 1, 3, 6, and 13 strip(s) each containing 21 tablets.

Not all mentioned pack sizes may be marketed.

Marketing authorization holder and manufacturer

Marketing authorization holder

Bayer B.V.

Siriusdreef 36

2132 WT Hoofddorp

For information:

Bayer B.V., P.O. Box 88, 2130 AB Hoofddorp

Manufacturers

Bayer AG

13342 Berlin, Germany

Bayer Weimar GmbH und Co. KG

Döbereinerstraße 20

99427 Weimar, Germany

Registered under RVG 23827.

This medicine is registered in the member states of the European Economic Area under the following names:

Belgium, Bulgaria, Cyprus, Denmark, Germany, Finland, Greece, Ireland, Iceland, Italy, Croatia, Luxembourg, Malta, Netherlands, Norway, Austria, Poland, Portugal, Romania, Spain, Sweden: Yasmin

France: Jasmine

Czech Republic, Hungary, Slovakia: Yadine

Estonia, Latvia, Slovenia: Yarina

This leaflet was last approved in October 2025.