

# **Yasmin<sup>®</sup>**

**drospirenone 3 mg,**

**ethinylestradiol 0.03 mg**

**PATIENT PACKAGE INSERT IN ACCORDANCE WITH THE  
PHARMACISTS' REGULATIONS (PREPARATIONS) - 1986**

The medicine is dispensed with a doctor's prescription only

**Yasmin<sup>®</sup>  
Film-coated Tablets**

Each film-coated tablet contains:  
drospirenone 3 mg  
ethinylestradiol 0.03 mg

Inactive ingredients and allergens: see section 6 “Further Information”.

**Read this leaflet carefully in its entirety before using the medicine.** This leaflet contains concise information about the medicine. If you have further questions, refer to the doctor or pharmacist.

This medicine has been prescribed for you. Do not pass it on to others. It may harm them even if it seems to you that their medical condition is similar.

Yasmin is not intended for women or adolescent girls who still have not had their first menstrual period.

**ESSENTIAL INFORMATION ABOUT COMBINED HORMONAL CONTRACEPTIVES AND ABOUT THE MEDICINE**

- When used properly, combined hormonal contraceptives are considered one of the most reliable reversible methods of contraception.
- They slightly increase the risk of a blood clot in the veins and arteries, especially in the first year or when resuming treatment with a combined hormonal contraceptive following a break of 4 or more weeks.

- You must be alert and refer to the doctor if you think you have symptoms of a blood clot (see “Blood clots” in section 2).

### **1) WHAT IS THE MEDICINE INTENDED FOR?**

Yasmin is intended to prevent pregnancy.

**Therapeutic group:** Yasmin belongs to a group of medicines called combined pills that contain 2 types of female hormones: estrogen (ethinylestradiol) and progestogen (drospirenone).

## **2) BEFORE USING THE MEDICINE**

### **Do not use the medicine if:**

- you are sensitive (allergic) to drospirenone or ethinylestradiol or to any of the other ingredients contained in the medicine. An allergic reaction may cause itching, rash, or swelling. For the list of inactive ingredients, see section 6 “Further Information”.
- You are pregnant or suspect that you are pregnant.
- you are suffering, or have suffered in the past, from a blood clot in a blood vessel of your leg (thrombosis of the deep veins, DVT), in your lungs (pulmonary embolism, PE) or in other organs of the body.

- you know you have a blood clotting disorder (for instance, protein C deficiency, protein S deficiency, antithrombin-III hereditary deficiency, Factor V Leiden or antiphospholipid antibodies).
- you have to undergo surgery or if you are immobile for a long time (see “Blood clots” in section 2).
- you have had a heart attack or stroke in the past.
- 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 ischemic attack (TIA – temporary stroke symptoms).

- you have any of the following diseases that may increase your risk of a blood clot in the arteries:
  - severe diabetes with blood vessel damage
  - very high blood pressure
  - very high blood fat levels (cholesterol or triglycerides)
  - a medical condition characterized by high blood levels of homocysteine (hyperhomocysteinemia)
- you are suffering, or have suffered in the past, from a type of migraine called “migraine with aura”.



- you have, or have had a liver disease, and your liver functions are not yet back to normal.
- you have impaired kidney function (kidney failure).
- you have, or have ever had, a liver tumor.
- you have, or have ever had, or there is suspicion for presence of breast cancer or cancer of the reproductive organs.
- you are suffering from unexplained vaginal bleeding.
- you are suffering from hepatitis C and taking medicinal products containing ombitasvir/paritaprevir/ritonavir and dasabuvir (see also “Drug interactions” section).

If you are suffering from one of the above-mentioned conditions, you must not use Yasmin. If you have any of the above-mentioned conditions, you must inform your doctor. The doctor will discuss with you other contraceptive methods that will better suit you.

**Special warnings regarding use of the medicine**

- Before you start taking Yasmin, read the information regarding blood clots further in this section. It is especially important that you read about the symptoms of a blood clot detailed later in section 2 “Blood clots”.
- This leaflet details a number of cases in which you must stop taking Yasmin, or cases in which the reliability of Yasmin may be reduced. In such cases, avoid sexual intercourse

or use additional, nonhormonal contraceptive measures, such as a condom or any other barrier contraceptive method. Do not rely on the “safe days” or body temperature measurement methods. These methods may be unreliable, since Yasmin affects the cyclic changes in body temperature and in cervical secretions.

- **Yasmin, like other hormonal contraceptives, does not protect against contraction of AIDS or any other sexually transmitted disease.**
- If you need to have blood tests, inform the doctor or the laboratory staff that you are taking an oral contraceptive pill, since hormonal contraceptives may affect the results of certain tests.

When should you contact the doctor?

Urgently seek medical attention

- if you notice possible signs of a blood clot that may indicate the formation in your body of a blood clot in the leg (i.e., deep vein thrombosis), a blood clot in the lungs (i.e., pulmonary embolism), a heart attack or a stroke (see “Blood clots” in section 2). For a description of the symptoms of these serious side effects, please see “How to recognize a blood clot” in section 2.

Talk to your doctor prior to taking Yasmin. In some situations, you must take special precautions while using Yasmin, or any other combination pill, and you may have to be

regularly checked by your doctor.

**Before using Yasmin, tell the doctor if any of the following conditions applies to you, develops or worsens while taking Yasmin.**

- 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 diabetes
- if you have depression
- if you have Crohn's disease or ulcerative colitis (chronic inflammatory bowel disease)
- if you have hemolytic uremic syndrome (HUS - a disorder of blood clotting causing kidney failure)

- if you have sickle cell anemia (an inherited disease of the red blood cells)
- if you have elevated fat levels in the blood (hypertriglyceridemia) or a family history of this condition. Hypertriglyceridemia has been associated with an increased risk of developing pancreatitis
- if you need to undergo surgery, or if you are immobile for a long time (see “Blood clots” in section 2)
- if you have recently given birth, you are at an increased risk of blood clots. Consult your doctor how soon after delivery you can start taking Yasmin
- if you have an inflammation in the veins under the skin (superficial thrombophlebitis)
- if you have varicose veins

- if you have epilepsy (see “Drug interactions” in section 2)
- if you have systemic lupus erythematosus (lupus - a disease affecting the immune system)
- if you have a disease that first appeared during pregnancy or during 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 ever had chloasma (a discoloration of the skin, especially on the face or neck known as “pregnancy patches”). If so, avoid exposure to direct sunlight or ultraviolet light

- if you have hereditary angioedema, estrogen-containing preparations may cause the symptoms of the disease or make them worse. Refer to a doctor immediately if you experience symptoms of angioedema such as swollen face, tongue and/or throat and/ or difficulty swallowing or hives (urticaria) together with breathing difficulties

### **Blood clots**

Using a combined hormonal contraceptive, such as Yasmin, increases your risk of developing a blood clot compared to the risk when not using one. In rare cases, a blood clot can block blood vessels and cause serious problems.

The risk level of thrombosis may vary in accordance with the type of pill you are taking.



Consult the doctor regarding the various options.

Blood clots may form:

- in the veins (a condition called 'venous thrombosis', 'venous thromboembolism' or VTE);
- in the arteries (a condition called '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 use of Yasmin is small.**

### **How to recognize a blood clot**

Urgently seek 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?
<ul style="list-style-type: none"><li>• swelling of one of the legs or along a vein in the leg or foot especially when accompanied by:<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 color of the skin of the leg, e.g., turning pale, red or blue</li></ul></li></ul>	Deep vein thrombosis

Are you experiencing any of these signs?	What are you possibly suffering from?
<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 lightheadedness or dizziness</li><li>• rapid or irregular heartbeat</li><li>• severe stomach pain</li></ul>	Pulmonary embolism

Are you experiencing any of these signs?	What are you possibly suffering from?
If you are unsure, talk to the doctor, as some of these symptoms, such as coughing or breathlessness, may be mistaken for milder conditions such as a respiratory tract infection (e.g., a common cold).	Pulmonary embolism

Are you experiencing any of these signs?	What are you possibly suffering from?
Symptoms which usually occur in one eye: <ul style="list-style-type: none"> <li>• sudden 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, or heaviness</li> <li>• sensation of squeezing or fullness in the chest, arm or below the breastbone</li> <li>• fullness, indigestion or feeling of choking</li> </ul>	Heart attack

Are you experiencing any of these signs?	What are you possibly suffering from?
<ul style="list-style-type: none"> <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 heartbeat</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> </ul>	Stroke

Are you experiencing any of these signs?	What are you possibly suffering from?
<ul style="list-style-type: none"><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

Are you experiencing any of these signs?	What are you possibly suffering from?
<p>Sometimes, the symptoms of stroke can be brief, with an almost immediate and full recovery, but you must still urgently seek medical attention, as you may be at risk of another stroke.</p>	<p>Stroke</p>
<ul style="list-style-type: none"> <li>• swelling and slight blue discoloration of the extremities</li> <li>• severe stomach pain (acute abdomen)</li> </ul>	<p>Blood clots blocking other blood vessels</p>



## **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 an increase in the risk of blood clots in the vein (venous thrombosis). However, these side effects are rare and most frequently 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 reaches the lung, it can cause a pulmonary embolism.
- Very rarely, a blood 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. In addition, the risk may be higher if you resume treatment with a combined hormonal contraceptive (the same product or a different product) following a break of 4 or more weeks.

After the first year, the risk declines, but will always be slightly higher than if you were not using a combined hormonal contraceptive.

When you stop using Yasmin, your risk of developing 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 venous thromboembolism (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 Yasmin 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 drospirenone, such as Yasmin, between about 9 to 12 women will develop a blood clot in a year.
- The risk of developing a blood clot will vary according to your personal medical history (see “Factors that increase your risk of a blood clot in a vein” and “Factors that increase your risk of a blood clot in an artery” in section 2).

	<b>Risk of developing a blood clot in a year</b>
Women who are not using a combined hormonal pill 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 Yasmin	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 Yasmin is low but some conditions will increase the risk. Your risk is higher:

- if you are significantly overweight (BMI over 30 kg/m<sup>2</sup>).
- if a member 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 50). In such a case, you could have a hereditary blood clotting disorder.
- if you need to undergo surgery, or if you are immobile for a long time because of an injury or illness, or you have your leg in a cast. The use of Yasmin may need to be stopped

several weeks before surgery or while you are less mobile. If you need to stop Yasmin, ask your doctor when you can start using it again.

- with increasing age (particularly above about the age of 35).
- if you gave birth less than a few weeks ago.

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

Air travel (more than 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 applies to you, even if you are unsure. Your doctor may decide that you should stop taking Yasmin.

If any of the above conditions changes while you are using Yasmin, for example, a close family member experiences a thrombosis for no known reason, or if 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 blood clot in an artery can cause serious problems. For example, a blood clot in an artery 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 Yasmin is very low but can increase:



- with increasing age (above about the age of 35).
- if you smoke. When using a combined hormonal contraceptive such as Yasmin, you are advised to stop smoking. If you are unable to stop smoking and are over 35 years of age, 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 (below the age of about 50). In this case, you may also carry an increased risk of having a heart attack or stroke.

- if you, or someone in your immediate family, have high blood fat levels (cholesterol or triglycerides).
- if you suffer from migraines, especially “migraine 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 one of them is particularly severe, the risk of developing a blood clot may be increased even more.

If one of the above conditions changes while you are using Yasmin, 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.

### **Yasmin and cancer**

Breast cancer has been observed slightly more often in women taking combined pills, but it is not known whether this increase is caused by the treatment with the pills. For example, it could be that more tumors are detected in women who take combination pills because they are examined by their doctor more often. The incidence of breast tumors gradually declines after discontinuing the combined hormonal contraceptive.

It is important you regularly check your breasts, and you must contact your doctor if you feel any lump.

In rare cases, benign liver tumors have been reported, and in even fewer cases, malignant liver tumors have been reported in patients who took contraceptive pills. Contact the doctor if you have unusually severe abdominal pain.

### **Psychiatric disorders**

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

**Bleeding between periods**

During the first few months of treatment with Yasmin, you may have unexpected bleeding (bleeding outside of the 7-day break). If this bleeding occurs for more than a few months, or if it begins after a few months of treatment, your doctor should examine what is wrong.

**What to do if no bleeding occurs during the break week**

If you have taken all the tablets correctly, have not vomited or had severe diarrhea and you have not taken any other medicines, it is unlikely that you are pregnant.

If the expected bleeding does not happen over two consecutive cycles, you may be pregnant. Contact the doctor immediately. Do not start treatment with a new strip until you are sure that you are not pregnant.

### **Drug interactions**

**If you are taking or have recently taken other medicines, including non-prescription medicines and nutritional supplements, tell the doctor or pharmacist.** Also inform the dentist or any other doctor who prescribes another medicine for you, that you are taking Yasmin. They will be able to tell you if you need to use an additional contraceptive (e.g., condom), and if so, for how long or whether the use of the other medicine you need to take should be changed. It is especially important to inform the doctor or pharmacist if you are taking:

Certain medicines that can

- have an influence on the blood levels of Yasmin

- cause Yasmin to be less effective in pregnancy prevention
- cause unexpected bleeding

This includes medicines used for the treatment of-

- epilepsy (e.g., primidone, phenytoin, barbiturates, carbamazepine, or oxcarbazepine)
- tuberculosis (e.g., rifampicin)
- AIDS (HIV) and hepatitis C infections (so-called protease inhibitors and non-nucleoside reverse transcriptase inhibitors such as ritonavir, nevirapine, efavirenz)
- fungal infections (griseofulvin, ketoconazole)
- arthritis, a joint disease resulting from erosion (arthrosis) (etoricoxib)

- pulmonary hypertension (bosentan)
- the herbal preparation Hypericum (St. John's Wort)

Use of Yasmin may influence the effect of other medicines such as:

- medicines containing cyclosporin
- lamotrigine to treat epilepsy (may lead to an increase in the frequency of seizures)
- theophylline to treat breathing problems
- tizanidine to treat muscle pain and/or muscle cramps

Do not use Yasmin if you are suffering from hepatitis C and taking medicinal products containing ombitasvir/paritaprevir/ritonavir and dasabuvir as this may lead to an increase



in the results of liver function blood tests (increase in the liver enzyme ALT). Your doctor will prescribe for you another type of contraceptive prior to starting treatment with these medicinal products. You can resume the use of Yasmin about 2 weeks after completing treatment with these products. See section 2 “Do not use the medicine if”.

**Girls and adolescent girls**

Yasmin is not indicated for use in women and adolescent girls who have not yet had their first menstrual period.

**Older women**

Yasmin is not intended for use after menopause.

**Women with liver impairment**

Do not take Yasmin if you suffer from liver disease. Please see also sections 'Do not use the medicine if' and 'Special warnings regarding use of the medicine'.

**Women with kidney impairment**

Do not take Yasmin if you are suffering from poor kidney function or kidney failure. Please see also sections 'Do not use the medicine if' and 'Special warnings regarding use of the medicine.'

**Use of the medicine and food**

The medicine can be swallowed on an empty stomach or with food, if necessary, with a small amount of water.

## **Pregnancy and breastfeeding**

### **Pregnancy**

If you are pregnant, you must not take Yasmin. If you became pregnant during the course of treatment with Yasmin, you must immediately stop taking Yasmin and contact your doctor. If you would like to become pregnant, you can stop taking Yasmin at any time (also see “If you stop taking the medicine” in section 3).

Consult your doctor or pharmacist prior to using any medicine.

### **Breastfeeding**

It is usually not recommended to take Yasmin when breastfeeding. If you want to take the

pill while breastfeeding, contact your doctor.

Use of Yasmin while breastfeeding may lead to a reduction in the volume of milk produced and change its composition. Tiny quantities of the active substances are secreted in breast milk. These quantities may affect the baby.

Consult your doctor or pharmacist prior to using any medicine.

### **Driving and use of machines**

There is no information suggesting that use of Yasmin affects driving or the use of machines.

### **Smoking**

It is recommended that you stop smoking when using a combined hormonal contraceptive

such as Yasmin. If you cannot stop smoking and you are over the age of 35 years, your doctor may recommend that you use a different type of contraceptive.

**Important information regarding some of the ingredients of the medicine**

Yasmin contains lactose.

If you suffer from intolerance to certain sugars, refer to the doctor before you start taking the medicine.

### **3) HOW SHOULD YOU USE THE MEDICINE?**

Always use according to the doctor's instructions. Check with the doctor or pharmacist if you are uncertain.

- The dosage and the treatment regimen will be determined by the doctor only. The usual dosage is generally one tablet every day, at a set time, for 21 days.

#### **Do not exceed the recommended dose**

Swallow the medicine whole; with water if necessary.

Do not crush/halve/chew the tablet, so as not to damage the coating of the tablet, and for fear that the dosage will not be precise.

- Each Yasmin strip contains 21 film-coated tablets; each one is marked, on the back of

the strip, with a day of the week.

- Start by taking the tablet marked with the appropriate day of the week.
- Continue taking the tablets in the direction of the arrows until the strip is finished.
- After 21 days of taking the tablets, take a 7-day break, namely, if you took the last tablet on Friday, take the first tablet of the next strip on Saturday of the next week.

Within a few days of taking the last tablet, menstrual bleeding will appear. The bleeding may not stop when you begin taking the tablets from the next strip. If you took the tablets correctly and start the next strip on time, you are protected from pregnancy and there is no need to use additional contraception during these 7 days.

- Start taking the tablets in the next strip after a 7-day break, even if menstrual bleeding continues. Be sure to begin taking tablets from the new strip on time. During the 7-day break, when you take no tablets, menstrual bleeding should occur. This bleeding usually starts on the 2nd or 3rd day after taking the last Yasmin tablet. Start the next strip after the 7th pill-free day, whether the bleeding has stopped or not.

**When can you start using the first strip?**

- *If you did not use a hormonal contraceptive in the previous month*  
Start taking Yasmin on the first day of the cycle (this is the first day of menstrual bleeding). In this case, you are immediately protected from pregnancy. You can also begin between



days 2-5 of menstrual bleeding, but in this case, an additional contraceptive (e.g., a condom) must be used during the first 7 days of taking Yasmin.

- *Switching from another combined oral contraceptive pill, or combined (vaginal) ring or patch*  
You can start taking Yasmin on the day after taking the last active tablet of the previous pill (the last tablet that includes active ingredients), but no later than the day after taking the last inactive pill of the previous contraceptive pill (or after taking the last inactive tablet of the previous pill). If you are switching from a combined (vaginal) ring or patch, consult the doctor.
- *Switching from a progestogen-only contraceptive (pills, contraceptive injections or intrauterine device)*

You may switch from the progestogen-only pill to Yasmin on any day you wish (start taking Yasmin at the time of the next scheduled injection or on the day the intrauterine device is removed), but in all of these cases, you must use an additional contraceptive (e.g., a condom) during the first 7 days of taking Yasmin.

- *After an abortion or miscarriage*

If you have had a miscarriage or abortion during the first three months of pregnancy, your doctor may tell you to start taking Yasmin straight away. In such a case, you will have contraceptive protection with the first tablet.

- *After having a baby*

You can start taking Yasmin between days 21 and 28 after having a baby. If you start later than day 28, use a barrier contraceptive (e.g., a condom) during the first 7 days of using Yasmin. If, after having a baby, you have had sex before starting Yasmin, you must be sure that you are not pregnant or wait until your next period.

- *If you are breastfeeding and want to start taking Yasmin*

Read “Pregnancy and breastfeeding” in section 2.

Consult with the doctor if you are not sure when to start taking Yasmin.

### **Tests and follow-up**

Before commencing use of Yasmin, your doctor will ask you questions regarding your and

your close family's medical history. The doctor will measure your blood pressure and may perform other tests, in accordance with your medical condition.

If you have blood tests done, tell the medical staff that you are taking Yasmin, as contraceptive pills can affect the results of some of these tests.

**If you accidentally take too high a dosage**

There are no reports of serious harmful results of taking too many Yasmin tablets.

If you accidentally took several Yasmin tablets at once, you may suffer from nausea, vomiting or vaginal bleeding. Such bleeding may also appear in girls who have not yet had their first menstrual period and have accidentally taken the medicine.

If you took an overdose, or if a child has accidentally swallowed the medicine, immediately refer to a doctor or proceed to a hospital emergency room and bring the package of the medicine with you.

**If you forget to take one or more Yasmin tablets**

- If the delay in taking a tablet is less than 12 hours, the protection against pregnancy is not reduced. Take the tablet as soon as you can and then continue taking the rest of the tablets as usual, at your set time.
- If the delay in taking a tablet is more than 12 hours, the protection against pregnancy may be reduced. The greater the number of tablets you have forgotten, the greater is the

risk of becoming pregnant.

The risk of incomplete protection against pregnancy is greater if you forget a tablet at the beginning or at the end of the strip. Therefore, keep to the following rules (see the diagram later in the leaflet):

- **You forgot more than one tablet in a strip**

Consult the doctor.

- **You forgot to take one tablet between days 1-7**

Take the forgotten tablet as soon as possible, even if that means that you have to take 2 tablets at the same time. Continue taking the rest of the tablets as usual and use **additional contraceptives** (e.g., a condom) for the next 7 days. If you have had sex

in the week before the day you forgot the tablet, you may be pregnant. In that case, consult the doctor.

○ **You forgot to take one tablet between days 8-14**

Take the forgotten tablet as soon as possible, even if that means that you have to take 2 tablets at the same time. Continue taking the rest of the tablets as usual. The protection against pregnancy is not reduced, and there is no need for use of additional contraceptives. If you forgot more than one tablet, use an additional barrier contraceptive, such as a condom, for 7 days.

○ **You forgot to take one tablet between days 15-21**

You can choose between two possibilities:

1. Take the forgotten tablet as soon as possible, even if that means that you have to take 2 tablets at the same time. Continue taking the rest of the tablets as usual. Instead of taking a 7-day break, start the next strip immediately after you have taken the last tablet from the previous strip (the start day will change). Most likely, you will have a period at the end of the second strip, but you may have bleeding or spotting while using the second strip.



2. You can also stop taking the tablets immediately and start counting the 7-day break (**record the day on which you forgot your tablet**). If you want to start a new strip on the day you normally start, the tablet-free break can be shortened to less than 7 days.

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

- If you have forgotten any of the tablets in a strip, and you do not have a bleeding during the first few days of the 7-day break, you may be pregnant. Refer to the doctor before you start the next strip.

### "I forgot to take" Flowchart

You forgot to take more than one tablet in a strip

You forgot to take only one tablet (a delay of more than 12 hours in taking)

Days 1-7

Consult with the attending doctor.

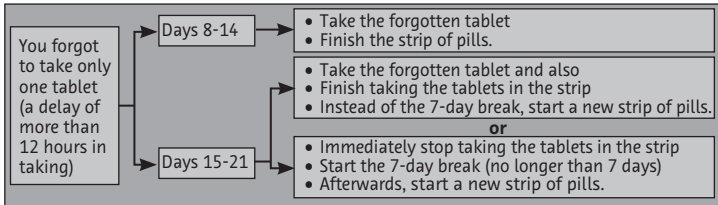
Yes

You had sexual intercourse in the week preceding the day you forgot to take the tablet?

No

- Take the forgotten tablet
- Use a condom for the following 7 days
- Also Finish the strip of pills.

*chart continued on next page*



**What to do in the case of vomiting or severe diarrhea**

If you vomit within 3-4 hours of taking the tablet or you have severe diarrhea, there is a risk that the active ingredients in the tablet will not be fully absorbed by your body. The situation is similar to a case in which you forget a tablet. After vomiting or diarrhea, take another tablet from a reserve strip as soon as possible. If possible, take it within 12 hours of when you normally take the tablet. If that is not possible or more than 12 hours have passed, follow the instructions given under “If you forget to take one or more Yasmin tablets”.

**Delaying your period: what you need to know**

Although it is not recommended, you can delay your period by skipping the 7-day break and consecutively taking a new strip of Yasmin until finishing it. You may experience light

or menstruation-like bleeding while using the second strip. After the usual 7-day break, start the next strip.

Consult the doctor before deciding to delay your period.

**Changing the first day of your period: what you need to know**

If you take the tablets according to the instructions, then your period will begin during the 7-day break.

If you have to change this day, make the pill-free period shorter – (but never extend it – 7 days is the maximum!).

For example, if you start the 7-day break 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 shorten the

pill-free period to 3 days or less, you may not have any bleeding during this time. You may experience light or menstruation-like bleeding.

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

**If you stop taking the medicine**

You can stop taking Yasmin whenever you want. If you do not want to become pregnant, ask the doctor for advice about other reliable methods of contraception. If you want to become pregnant, stop taking Yasmin and wait for a natural menstrual period before trying to become pregnant. You will be able to calculate the expected delivery date more easily.

Adhere to the treatment as recommended by the doctor.

**Do not take medicines in the dark! Check the label and the dose each time you take medicine. Wear glasses if you need them.**  
**If you have further questions regarding use of the medicine, consult your doctor or pharmacist.**

#### **4) SIDE EFFECTS**

As with any medicine, use of Yasmin may cause side effects in some users. Do not be alarmed when reading the list of side effects. You may not suffer from any of them.

If you have any side effect, especially if it is severe or prolonged, or if there is any change in your health, that you think can be related to Yasmin, please talk to your doctor.

An increased risk of blood clots in the veins (venous thromboembolism [VTE]) or blood clots in the arteries (arterial thromboembolism [ATE]) exists in all women taking combined hormonal contraceptives. For more detailed information on the different risks arising from taking combined hormonal contraceptives, please see section 2 “Before Using the Medicine”.



The following side effects have been linked with use of Yasmin:

**Stop using the medicine and contact the doctor immediately if you experience the following serious side effects**

**Signs suggesting an allergic reaction to Yasmin:**

– swelling of the face, lips, mouth, tongue and/or throat.

**Signs suggesting breast cancer include:**

– dimpling of the skin.

– changes in the nipple.

– any lumps that can be seen or felt.

**Signs suggesting cancer of the cervix include:**

- vaginal discharge that contains blood or smells of blood.
- unusual vaginal bleeding.
- pelvic pain.
- painful sex.

**Signs suggesting severe liver problems include:**

- severe pain in the upper abdomen.
- yellowing of the skin or eyes (jaundice).
- inflammation of the liver (hepatitis).
- itching all over the body.

If you think you may have any of these side effects, refer to a doctor straight away. You may need to stop taking the medicine.

**Additional side effects**

Common side effects – effects occurring in 1-10 out of 100 users

- breast pain, breast tenderness, menstrual disorders, bleeding between periods
- headache, depressed mood
- migraine
- nausea
- thick white vaginal discharge, vaginal fungal infection.

Uncommon side effects – effects occurring in 1-10 out of 1,000 users

- breast enlargement.
- altered interest in sex.
- high blood pressure, low blood pressure.
- vomiting, diarrhea.
- acne, severe itching, severe skin rash, hair loss (alopecia)
- vaginal infection.
- fluid retention.
- body weight changes.

Rare side effects – effects occurring in 1-10 out of 10,000 users

- allergic reaction (hypersensitivity), asthma
- breast secretions.
- hearing impairment
- erythema nodosum (a skin condition characterized by painful reddish skin nodules), erythema multiforme (a skin condition characterized by rash, including target-shaped reddening or sores).
- harmful blood clots in a vein or artery for example:
  - o in a leg or foot (deep vein thrombosis)
  - o in a lung (pulmonary embolism)

- heart attack
- stroke
- mini-stroke or temporary stroke-like symptoms, known as a transient ischemic attack (TIA)
- blood clots in the liver, stomach or intestine, in the kidneys or eyes

The chance of having a blood clot may be higher if you have any other condition that increases this risk (for more information on conditions increasing the risk of a blood clot and symptoms of a blood clot, see section 2).

If you experience any side effect, if any side effect gets worse, or if you experience a side effect not mentioned in this leaflet, consult your doctor.

Side effects can be reported to the Ministry of Health by clicking on the link “Report Side Effects of Drug Treatment” found on the Ministry of Health homepage ([www.health.gov.il](http://www.health.gov.il)) that directs you to the online form for reporting side effects, or by entering the link: <https://sideeffects.health.gov.il>

## **5) HOW SHOULD THE MEDICINE BE STORED?**

- Avoid poisoning! This medicine and any other medicine must be kept in a safe place out of the reach and sight of children and/or infants to avoid poisoning. Do not induce vomiting unless explicitly instructed to do so by the doctor.
- Do not use the medicine after the expiry date (exp. date) that appears on the package. The expiry date refers to the last day of that month.
- Store at a temperature below 25°C.
- Do not discard medicines in the toilet or waste bin. Consult a pharmacist regarding how to discard of medicines you no longer need. These measures will help protect the environment.



## **6) FURTHER INFORMATION**

- In addition to the active ingredients, the medicine also contains:  
Lactose monohydrate, maize starch, pregelatinized starch (from maize starch), povidone, magnesium stearate, hypromellose, macrogol 6000, talc, titanium dioxide (E171), ferric oxide pigment - yellow (E172).

Each tablet contains: 48.17 mg lactose monohydrate

- What does the medicine look like and what are the contents of the package?  
Yasmin tablets are film-coated, round, light-yellow, biconvex, with “*DO*” embossed inside a hexagon on one side.

The tablets are provided in blister (tray) strips of 21 tablets. Each package contains 1 or 3 strips.

Not all packages may be marketed.

- **Registration holder and address:** Bayer Israel Ltd., 36 Hacharash St., Hod Hasharon 4527702.
- **Manufacturer name and address:** Bayer AG, Berlin, Germany.
- Revised in March 2021 according to MOH guidelines
- Registration number of the medicine in the National Drug Registry of the Ministry of Health: 122 02 30220 00