Yasmin* 0.03 mg / 3 mg film-coated tablets

Read all of this leaflet carefully before you start taking this medicine.

1. WHAT IS YASMIN AND WHAT IT IS USED FOR

Yasmin is a combination pill that is used to prevent pregnancy.

Each tablet contains a small amount of two different female hormones, namely ethinylestradiol and levonorgestrel.

Combination pills that contain two hormones are called “combination” pills.

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE YASMIN

General notes

Before you can begin taking Yasmin, 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 heart rate and ask about your medical history.

In this leaflet, several situations are described where you should stop using Yasmin, or where the reliability of Yasmin may be decreased. In such situations you should either not have sex or you should take any non-hormonal contraceptives that your doctor recommends. A contraceptive method must be used for seven days after stopping Yasmin. Do not use rhythm or temperature methods. These methods can be unreliable because they cannot be used in case of irregular bleeding. The use of combination pills has been connected with an increase of the risk of an arterial or venous blood clot (arterial thrombosis), for example, in the blood vessels of the heart (heart attack) or the brain (stroke). The risk of an arterial blood clot in users of combination pills increases:

- If you smoke. You are strongly advised to stop smoking when you use Yasmin, especially if you are over 35 years.
- If the fat content of your blood is increased (cholesterol or triglycerides)
- If you are overweight
- If you have a disturbance of blood clotting (for example, protein C deficiency)
- If you have a disease that may increase the risk of a blood clot in the arteries. This applies to the following diseases:
  - Diabetes with damaged blood vessels
  - Very high blood pressure
  - Very high level of fat in the blood (cholesterol or triglycerides)
  - A disease that can be an indicator of a heart attack in the future (for example, angina pectoris which causes severe pain in the chest) or of a stroke (for example, a passing slight stroke with no residual effects).
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    - Diabetes with damaged blood vessels
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    - A disease that can be an indicator of a heart attack in the future (for example, angina pectoris which causes severe pain in the chest) or of a stroke (for example, a passing slight stroke with no residual effects).

3. HOW TO TAKE YASMIN

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In this leaflet, several situations are described where you should stop using Yasmin, or where the reliability of Yasmin may be decreased. In such situations you should either not have sex or you should take any non-hormonal contraceptives that your doctor recommends. A contraceptive method must be used for seven days after stopping Yasmin. Do not use rhythm or temperature methods. These methods can be unreliable because they cannot be used in case of irregular bleeding. The use of combination pills has been connected with an increase of the risk of an arterial or venous blood clot (arterial thrombosis), for example, in the blood vessels of the heart (heart attack) or the brain (stroke).

The use of any combination pill, including Yasmin, increases a woman’s risk of developing a venous blood clot (venous thrombosis) compared with women who do not take any contraceptive pill. The risk of a venous blood clot in users of combination pills increases:

- With increasing age
- If you are overweight
- If one of your close relatives has ever had a blood clot in the leg, lung (pulmonary embolism), or deep veins of the arm or leg
- If you have had severe accident or if you are immobilized for a long time. It is important to tell your doctor that you are using Yasmin as you may have to stop taking it. Your doctor will tell you when to start again. This is usually about two weeks after you are back on your feet.

Your chances of having a blood clot are increased by taking the Pill:

- Of 100,000 women who are not on the pill and not pregnant, about 5-10 may have a blood clot in a year.
- Of 100,000 women taking a Pill like Yasmin, 30-40 may have a blood clot in a year, the exact number is unknown.
- Of 100,000 women who are pregnant, around 60 may have a blood clot in a year.

A blood clot in the veins may travel to the lungs and may block blood vessels (called a lung embolus). Formation of blood clots in the veins may be fatal in 1-2% of cases. The level of risk may vary according to the type of pill you take. Discuss with your doctor the available options.

The use of combination pills has been connected with an increase of the risk of an arterial blood clot (arterial thrombosis), for example, in the blood vessels of the heart (heart attack) or the brain (stroke).

The risk of an arterial blood clot in users of combination pills increases:

- If you smoke. You are strongly advised to stop smoking when you use Yasmin, especially if you are over 35 years.
- If the fat content of your blood is increased (cholesterol or triglycerides)
- If you are overweight
- If you have a disturbance of blood clotting (for example, protein C deficiency)
- If you have a disease that may increase the risk of a blood clot in the arteries. This applies to the following diseases:
  - Diabetes with damaged blood vessels
  - Very high blood pressure
  - Very high level of fat in the blood (cholesterol or triglycerides)
  - A disease that can be an indicator of a heart attack in the future (for example, angina pectoris which causes severe pain in the chest) or of a stroke (for example, a passing slight stroke with no residual effects).

Stop taking Yasmin and contact your doctor immediately if you notice possible signs of a blood clot, such as:

- Severe pain and/or swelling in one of your legs
- Sudden severe pain in the chest which may reach the arm
- Sudden breathlessness
- Sudden cough without an obvious cause
- Any unusual, severe or long-lasting headache or worsening of migraine
- Partial or complete blindness or double vision
- Difficulty in speaking or inability to speak
- Giddiness or fainting
- Weakness, strange feeling, or numbness in any part of the body

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

Bleeding between periods

During the first few months that you are taking Yasmin, you may have unexpected bleeding (bleeding outside the gap week). 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 to do if no bleeding occurs during the gap week

If you have taken all the tablets correctly, have not had vomiting or severe diarrhoea and you have not taken any other medicines, it is highly unlikely that you are pregnant. If the expected bleeding does not happen twice in succession, you may be pregnant. Contact your doctor immediately. Do not start the next strip until you are sure that you are not pregnant.

Other medicines and Yasmin

Always tell your 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 Yasmin. They can tell you if you need to take additional contraceptive precautions (for example condoms) and if so, for how long.

Some medicines can make Yasmin less effective in preventing pregnancy, or can cause unexpected bleeding. These include:

- Medicines used for the treatment of:
  - Epilepsy (e.g. primidone, phenytoin, barbiturates, carbamazepine, oxcarbazepine)
  - Tuberculosis (e.g. isoniazid).
  - HIV infections (ritonavir, nevirapine) or other infections (antibiotics such as griseofulvin, penicillin, tetracycline)
  - High blood pressure in the blood vessels in the lungs (bosentan)

- The herbal remedy St. John’s wort

Yasmin may influence the effect of other medicines, e.g.

- Medications containing chlorpheniramine (this could lead to an increased frequency of seizures)

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

Yasmin and food and drink

Yasmin will 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

If you are pregnant, do not take Yasmin. If you become pregnant while taking Yasmin stop immediately and contact your doctor. If you want to become pregnant, you can stop taking Yasmin at any time (see also “If you want to stop taking Yasmin”).

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

Breast-feeding

Use of Yasmin 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.

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

Driving and using machines

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

Yasmin contains lactose

If you cannot tolerate certain sugars, contact your doctor before you take Yasmin.
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 example, a condom) for the first 7 days.

2. If you use Yasmin in this manner, you are also protected against pregnancy during the 7 days when you are not taking a tablet.

3. HOW TO TAKE YASMIN

Each tablet contains 3 milligrams drospirenone and 0.030 milligram ethinylestradiol · Other active substances in the pill will not be fully taken up by 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 when you normally take your pill. If that is not possible or 12 hours have passed, you should follow the advice given under “If you forget to take Yasmin”.

Delaying your period: what you need to know

If you forget the tablets according to the instructions, then your period will begin during the tablet-free week. If you have to change this day, reduce the number of tablet-free days (but never increase them – 7 is the maximum). 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.

If you stop taking Yasmin

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

What to do in the case of vomiting or severe diarrhoea

If you vomit within 3-4 hours after taking a tablet or you have severe diarrhoea, there is a risk that the active substances in the pill will not be fully taken up by 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 when you normally take your pill. If that is not possible or 12 hours have passed, you should follow the advice given under “If you forget to take Yasmin”.

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

If you use Yasmin 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 Yasmin on the first day of the cycle (that is, the first day of your period). If you start Yasmin 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 a combination hormonal contraceptive, or combination contraceptive vaginal ring or patch

  You can start Yasmin preferably on the day after the last active tablet (the last tablet containing the 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).

  When changing from a combination contraceptive vaginal ring or patch, follow the advice of your doctor.

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

  You may switch any day after 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

  You can start Yasmin 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 Yasmin use. If you have a baby you have had sex before starting Yasmin (again), be sure that you are not pregnant or wait until your next period.

  • If you are breastfeeding and want to start Yasmin (again) after having a baby

  Read the section on “Breast feeding”.

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

If you take more Yasmin than you should

The leaflet contains reports of harmful and beneficial effects, and results of taking too many Yasmin tablets.

If you take several tablets at once then you may have symptoms of nausea or vomiting. Young girls may experience bleeding from the vagina.

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

If you forget to take Yasmin

• 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 follow the tablets taking the tablet 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 at 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

  Use a barrier method (for example, a condom) during the first seven days of Yasmin use.

  • 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

  Follow the advice of your doctor.

  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 the gap week you may be pregnant. In that case, contact your doctor.

  2. If you have forgotten any of the tablets in a strip, and you do not have a bleeding during the first tablet-free period, you may be pregnant. Contact your doctor before you start the next strip.

  3. Only 1 tablet forgotten (taken more than 12 hours late)

  Ask your doctor for advice

  • Take the forgotten tablet and

  • Finish the strip

  • Start the next strip

  • Stop the strip immediately

  • Begin the gap week (not longer than 7 days, including the forgotten tablet)

  • Then start the next strip

  • More than one tablet forgotten in 1 strip

  Ask your doctor for advice

  • Take the forgotten tablet and

  • Finish the strip

  • Start the next strip

  • Or

  • In week 1

  • Only 1 tablet forgotten (taken more than 12 hours late)

  No

  • Had sex in the previous week before forgetting?

  Yes

  • Take the forgotten tablet

  • Finish the strip

  • Start of the gap week

  • In week 2

  • In week 3

  • Stop the strip immediately

  • Begin the gap week (not longer than 7 days, including the forgotten tablet)

  • Then start the next strip

  ・ What Yasmin looks like and content of the pack

  Yasmin tablets are film-coated tablets; the core of the tablet is coated. The tablets are light yellow, round, with convex surfaces, one side is embossed with the letters “DO” in a regular hexagon. Yasmin is available in packs of 1, 3, 6 and 13 blisters each with 21 tablets. Not all pack sizes may be marketed.

  Marketing Authorisation Holder

  Bayer Limited, The Atrium, Blackthorn Road, Dublin 18

  Manufacturer

  Bayer Pharma AG

  13342 Berlin, Germany

  This medicinal product is authorised in the Member States of the EEA under the following names:

  • Austria, Belgium, Denmark, Finland, Germany, Greece, Iceland, Ireland, Italy, Luxembourg, Norwegian, Norway, Portugal, Spain, Sweden, United Kingdom: Yasmin

  • France: Jasmine

  This leaflet was prepared by PCO Manufacturing in August 2014

Uncommon side effects (between 1 and 10 in every 1,000 users may be affected):

• breast enlargement, changes in interest in sex

• high blood pressure, low blood pressure

• mood, irritability

• skin, rash, severe itching, hair loss (alopecia)

• infection of the vagina

• fluid retention and body weight changes.

Rare side effects (between 1 and 10 in every 10,000 users may be affected):

• allergic reactions (hypersensitivity), asthma

• breast secretion

• hearing impairment

• blockage of a blood vessel by a clot formed elsewhere in the body

Common side effects

• menstrual disorders, bleeding between periods, breast pain, breast tenderness

• headache, depressive mood

• migraine

• nausea

• thick, whitish vaginal discharge and vaginal yeast infection.

What to do in the case of vomiting or severe diarrhoea

If you vomit within 3-4 hours after taking a tablet or you have severe diarrhoea, there is a risk that the active substances in the pill will not be fully taken up by 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 when you normally take your pill. If that is not possible or 12 hours have passed, you should follow the advice given under “If you forget to take Yasmin”.

Delaying your period: what you need to know

Even though it is not recommended, you can delay your period by going straight to a new strip of Yasmin 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 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 tablet free week. If you have to change this day, reduce the number of tablet-free days (but never increase them – 7 is the maximum). 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.

If you stop taking Yasmin

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

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. The following is a list of the side effects that have been linked with the use of Yasmin: