Yasmin® 0.03 mg / 3 mg film-coated tablets
Ethinylestradiol / Drospirenone

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

- Keep this leaflet, you may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

Important things to know about combined hormonal contraceptives (CHCs):

- They are one of the most reliable reversible methods of contraception if used correctly.
- They slightly increase the risk of developing a blood clot in the veins and arteries, especially in the first year or when restarting a combined hormonal contraceptive following a break of 4 or more weeks.

Please be alert and see your doctor if you think you may have symptoms of a blood clot (see section 2: ‘Blood clots’).

What is in this leaflet
1. WHAT YASMIN IS AND WHAT IT IS USED FOR
2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE YASMIN
   a. When you should not use Yasmin
   b. Warnings and precautions
   c. Blood clots
   d. Changes in the first day of your period: what you need to know
3. POSSIBLE SIDE EFFECTS
4. 5. HOW TO STORE YASMIN
6. CONTENTS OF THE PACK AND OTHER INFORMATION

1. WHAT YASMIN IS AND WHAT IT IS USED FOR

- Yasmin is a contraceptive pill and is used to prevent pregnancy.
- Each tablet contains a small amount of natural female hormones, namely drospirenone and ethinylestradiol.
- Contraceptive pills that contain two hormones are called “combination” pills.

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE YASMIN

General notes

Before you start using Yasmin, you should read the information on blood clots in section 2. It is particularly important to note the symptoms of a blood clot – see section 2: “Blood clots”.

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 depending upon your personal situation, may also carry out other tests.

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 use a non-hormonal contraceptive precaution, e.g., use a condom or another barrier method. Do not use rhythm or withdrawal methods. These methods can be unreliable because Yasmin alters the monthly changes of body temperature and of the cervical mucus.

Yasmin, like other hormonal contraceptives, does not protect against HIV infection (AIDS) or any other sexually transmitted disease.

When you should not use Yasmin

You should not use Yasmin if you have any of the conditions listed below. If you do have any of the conditions listed below, you must not take Yasmin. Your doctor will discuss with you what other form of birth control would be more appropriate.

Do not use Yasmin:

- If you have (or have ever had) a blood clot in a blood vessel and arteries, especially in the first year or when restarting a combined hormonal contraceptive following a break of 4 or more weeks.
- If you have had a stroke or a blood clot in the veins.
- If you have had any of the following conditions that may increase your risk of a blood clot in the arteries or veins in the first year of use of a combined hormonal contraceptive.
- If you have (or have ever had) a condition that may increase your risk of blood clots (see section 5: “Possible Side Effects”).
- If you have any of the conditions listed in section 2: “Blood clots”.
- If you have ever had high blood pressure.
- If you have a disease that may increase your risk in the first year of use of a combined hormonal contraceptive.
- If you have any of the conditions listed in section 2: “Blood clots”.
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If you have any of the conditions listed in section 2: “Blood clots”, you may need to take special care while using Yasmin. The risk depends on your natural risk of VTE and the type of combined hormonal contraceptive you are taking.

The overall risk of a blood clot in the leg or lung (DVT or PE) with Yasmin is small.

- Out of 10,000 women who are not using any combined hormonal contraceptive and are not pregnant, about 12 out of 10,000 women using a combined hormonal contraceptive have a blood clot in a vein higher in the body in the first year of use of Yasmin.

- The risk of developing a blood clot in a vein is highest during the first year of taking a combined hormonal contraceptive for the first time. The risk may also be higher if you restart taking combined hormonal contraceptives (the pill) after a break of 4 weeks or more.

- After the first year, the risk gets smaller but is always slightly higher than if you were not using a combined hormonal contraceptive.

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- Women who are not using a combined hormonal pill and are pregnant.

- Women using a combined hormonal contraceptive pill containing drospirenone or norgestimate.

The risk of a blood clot with Yasmin is small but some conditions will increase the risk. Your risk is higher:

- If you are very overweight (body mass index or BMI over 30 kg/m²)
- If you have had a history of deep vein thrombosis (DVT), pulmonary embolism (PE), or pulmonary embolism with DVT, or have varicose veins
- If you have blood clots.
- If you have a disease that may increase your risk in the first year of use of a combined hormonal contraceptive.

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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, e.g. the active tablet on the day after the tablet free days of your previous pill or after the last inactive tablet of your previous pills. When changing from a combination contraceptive vaginal ring or patch, follow the advice of your doctor.
- Changing from a progestogen-only method to the combined hormonal contraceptive
- If you take 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 7 days of Yasmin use.
- If, after having 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 get pregnant
- Ask your doctor what to do if you are not sure when to start.
- If you want to take Yasmin before you
- There are no reports of serious harmful 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 have 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 take the following tablets again at the usual time.
- If you are more than 12 hours late taking a tablet, the protection against pregnancy may be reduced. The greater the number of tablets that you have forgotten, the greater is the risk of becoming pregnant.
- If you forget to take the first day's tablet, prevent pregnancy by using another method of contraception for the remainder of your cycle. If you forget to take a tablet in 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
- Contact your doctor.
- One tablet forgotten in week 1
- Take the forgotten tablet as soon as you remember, even if that means that you have to take two tablets at the same time. Continue taking the tablets at the usual time and use extra precautions for the next 7 days, for example, a condom. If you have had sex in the week before forgetting the tablet you may be pregnant. In that case, contact your doctor.
- One tablet forgotten in week 2
- Take the forgotten tablet as soon as you remember, even if that means that you have to take two tablets at the same time. Continue taking the tablets at the usual time. The protection against pregnancy is not reduced, but it may be reduced. 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 do not have a bleeding during the first tablet-free period, you may be pregnant. Contact your doctor before you start your next period.

More than 1 tablet forgotten in 1 strip
- Ask your doctor for advice
- More than 1 tablet forgotten in 1 strip
- week 1
- Yes
- No
- Has had sex in the previous week before forgetting?
- Take the forgotten tablet
- Use a barrier method (condom) for the following 7 days and
- Finish the strip
- Only 1 tablet forgotten (taken more than 12 hours late)
- week 2
- In week 2
- Take the forgotten tablet and
- Finish the strip
- Take the tablet free days of the gap week
- Start the next strip
- In week 3
- The strip is finished
- Stop the strip immediately
- The protection against pregnancy for the next 7 days, including the forgotten tablet)
- Then start the next strip

What to do in 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 of when you normally take your pill. If that is not possible or 12 hours have passed, contact your doctor immediately and follow the advice of your doctor.
- Delying 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 use the tablet free days of the first free period and finishing it. You may experience amenorrhoea-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 have 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

before surgery or while you are less mobile. If you need to stop Yasmin ask your doctor when you can start using it again.
- As you get older (particularly above about 35 years)
- If you gave birth less than a few weeks ago
- The risk of developing a blood clot increases the more conditions you have.
- With increasing age (beyond about 35 years)
- If you smoke. When using a combined hormonal contraceptive like Yasmin, you are advised to stop smoking if you are unable to stop smoking and are older than 35. Your doctor may advise you to use a different type of contraceptive
- If you are overweight
- With height or weight
- If you have high blood pressure
- If a member of your immediate family has had a heart attack or stroke at a young age (less than about 55 years)
- If you, or someone in your immediate family, have a high level of fat in the blood (cholesterol or triglycerides)
- If you get migraines, especially migraines with aura
- If you have a problem with your heart (valve disorder, disturbance of the rhythm called atrial fibrillation)
- If you have diabetes
- If you have more than one of these conditions or if any of them are particularly severe the risk of developing a clot may be increased even more.
- If any of the above conditions change 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.

BLOOD CLOTS IN AN ARtery
What happens if a blood clot forms in an artery?
- Like a blood clot in a vein, a clot in an artery can cause serious problems. For example, it can cause a heart attack or a stroke.

Factors that increase your risk of a blood clot in an artery
- It is important to note that the risk of a heart attack or stroke from using Yasmin is very small but can increase.
- With increasing age (beyond about 35 years)
- If you smoke. When using a combined hormonal contraceptive like Yasmin, you are advised to stop smoking if you are unable to stop smoking and are older than 35. Your doctor may advise you to use a different type of contraceptive
- If you are overweight
- With height or weight
- If you have high blood pressure
- If a member of your immediate family has had a heart attack or stroke at a young age (less than about 55 years)
- If you, or someone in your immediate family, have a high level of fat in the blood (cholesterol or triglycerides)
- If you get migraines, especially migraines with aura
- If you have a problem with your heart (valve disorder, disturbance of the rhythm called atrial fibrillation)
- If you have diabetes
- If you have more than one of these conditions or if any of them are particularly severe the risk of developing a clot may be increased even more.
- If any of the above conditions change 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
Yasmin contains the progestogen drospirenone. 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 oral contraceptives because they are by their nature more common. 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

when using Yasmin, ask your doctor what to do if you are not sure when to start.

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

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

Yasmin and food and drink
Yasmin may be taken with or without food, if necessary with a small amount of water.

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

Pregnancy
If you are pregnant, do not take Yasmin. If you become pregnant while taking Yasmin you must stop immediately and contact your doctor. If you want to become pregnant, you can stop taking Yasmin at any time (see also “If you 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.
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. If you get any side effect, particularly if severe and persistent, or have any change to your health that you think may be due to Yasmin, please talk to your doctor.

An increased risk of blood clots in your veins (venous thromboembolism (VTE)) or blood clots in your arteries (arterial thromboembolism (ATE)) is present for all women taking combined hormonal contraceptives. For more detailed information on the different risks from taking combined hormonal contraceptives please see section 2 "What you need to know before you take Yasmin".

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

Common side effects (between 1 and 10 in every 100 users may be affected):
- menstrual disorders, bleeding between periods, breast pain, breast tenderness
- headache, depressive mood
- migraine
- nausea
- thick, whitish vaginal discharge and vaginal yeast infection.

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
- vomiting, diarrhoea
- acne, 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
- the skin conditions erythema nodosum (characterized by painful reddish skin nodules) or erythema multiforme (characterized by rash with target-shaped reddening or sores).
- Harmful blood clots in a vein or artery for example:
  - In a leg or foot (i.e. DVT)
  - In a lung (i.e. PE)
  - Heart attack
  - Stroke
  - Mini-stroke or temporary stroke-like symptoms, known as transient ischaemic attack (TIA)
  - Blood clots in the liver, stomach/intestine, kidneys or eye.

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

Reporting of side effects
If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via HPRA Pharmacovigilance, Earlsfort Terrace, Dublin 2, Ireland, Tel: +353 1 6764971; Fax: +353 1 6762517; Website: www.hpra.ie; E-mail: medsafety@hpra.ie.

By reporting side effects you can help provide more information on the safety of this medicine.

5. HOW TO STORE YASMIN
Keep this medicine out of the sight and reach of children.

Do not store above 25 °C. Store in the original package.

Do not use this medicine after the date on the packaging after "Do not use after:" or "EXP.:", the expiry date refers to the last day of that month.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help to protect the environment.

6. CONTENTS OF THE PACK AND OTHER INFORMATION
What Yasmin contains
- The active substances are drospirenone and ethinylestradiol.
- Each tablet contains 3 milligrams drospirenone and 0.03 milligram ethinylestradiol
- Other ingredients (excipients) are lactose monohydrate, maize starch, pregelatinised maize starch, povidone K90, magnesium stearate, hypromellose, macrogol 6000, talc, titanium dioxide (E 171), iron oxide, yellow (E 172).

What Yasmin looks like and content of the pack
- Each blister of Yasmin contains 21 light yellow, film coated tablets
- 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 and 3 blisters each with 21 tablets.

Not all pack sizes may be marketed.

Manufacturer
Bayer Pharma AG, 13342Berlin, Germany or Bayer Pharma AG, 13353Berlin, Germany

This medicinal product is authorised in the Member States of the EEA under the following names:
- Austria, Belgium, Croatia, Denmark, Finland, Germany, Greece, Iceland, Ireland, Italy, Luxembourg, Netherlands, Norway, Portugal, Spain, Sweden, United Kingdom: Yasmin
- France: Jasmine

Product procured from within the EU, repackaged and distributed by the Parallel Product Authorisation Holder:
- PCO Manufacturing, Unit 10, Ashbourne Business Park, Rath, Ashbourne, Co. Meath.

Parallel Product Authorisation Number:
PFA 466/3261

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This leaflet was prepared by PCO Manufacturing in July 2016