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Due to regulatory changes, the content of the following Patient Information Leaflet may vary from the one found in your medicine pack. Please compare the 'Leaflet prepared/revised date' towards the end of the leaflet to establish if there have been any changes.

If you have any doubts or queries about your medication, please contact your doctor or pharmacist.

PACKAGE BOOKLET: INFORMATION FOR THE USER

Yasmin, 0.03 mg / 3 mg film-coated tablets

Ethinylestradiol / Drospirenone

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

- *Keep this booklet, 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, do not pass it on to others. It may harm them.*
- *If any of the side effects gets serious, or if you notice any side effects not listed in this booklet, please tell your doctor or pharmacist.*

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1. **WHAT YASMIN IS AND WHAT IT IS USED FOR**

- Yasmin is a contraceptive pill and is used to prevent pregnancy.
- Each light yellow 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. **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, depending upon your personal situation, may also carry out some other tests.

In this booklet, 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 extra non-hormonal contraceptive precautions, e.g. use a condom or another barrier method. Do not use rhythm or temperature methods. These methods can be unreliable because Yasmin alters the monthly changes of body temperature and 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

Do not take Yasmin

- if you have (or have ever had) a blood clot in a blood vessel of the leg (thrombosis), of the lung (pulmonary embolism) or other organs
- if you have (or have ever had) a heart attack or stroke
- if you have (or have ever had) 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)
- 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
 - a very high level of fat in the blood (cholesterol or triglycerides)
- if you have a disturbance of blood clotting (for example, protein C deficiency)
- if you have (or have ever had) a certain form of migraine (with so-called focal neurological symptoms)
- if you have (or have ever had) an inflammation of the pancreas (pancreatitis)
- if you have (or have ever had) liver disease and your liver function is still not normal
- if your kidneys are not working well (renal failure)
- if you have (or have ever had) had a tumour in the liver
- if you have (or have ever had) or if you are suspected of having breast cancer or cancer of the genital organs
- if you have any unexplained bleeding from the vagina

- if you are allergic to ethinylestradiol or drospirenone, or any of the other ingredients of Yasmin. This may cause itching, rash or swelling.

When to take special care with Yasmin

In some situations you need to take special care while using Yasmin or any other combination pill, and your doctor may need to examine you regularly. If any of the following conditions applies to you, tell your doctor before starting to use Yasmin. Also, if any of the following applies or if any of the conditions develops or worsens while you are taking Yasmin consult your doctor:

If you have:

- a close relative who has ever had breast cancer
- a disease of the liver or the gallbladder
- diabetes
- depression
- Crohn's disease or inflammatory bowel disease (ulcerative colitis)
- a blood disease called HUS (haemolytic uraemic syndrome) that causes kidney damage
- a blood disease called sickle cell anaemia
- epilepsy (see page 5 "Yasmin and using other medicines")
- a disease of the immune system called SLE (systemic lupus erythematosus)
- a disease that first appeared during pregnancy or earlier use of sex hormones (for example, hearing loss, a blood disease called porphyria, yellowing of the skin or eyes (jaundice), itching of the whole body (pruritis), skin rash with blisters during pregnancy (gestational herpes), a nerve disease causing sudden movements of the body (Sydenham's chorea)
- ever had a discolouration of the skin especially on the face or neck known as "pregnancy patches" (chloasma). If so, avoid direct sunlight or ultraviolet light.
- hereditary angioedema, products containing oestrogens may cause or worsen the symptoms. You should see your doctor immediately if you experience symptoms of angioedema such as swollen face, tongue and/or throat and/or difficulty swallowing or hives together with difficulty breathing.

Yasmin and venous and arterial blood clots

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 other organ at a young age
- if you need to have surgery, if you have had a serious accident or if you are immobilised for a long time. It is important to tell your doctor that you are taking 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 older than 35 years.**
- have an increased fat content of your blood (cholesterol or triglycerides)
- are overweight
- have a close relative who ever had a heart attack or stroke at a young age
- have high blood pressure
- suffer from migraine
- have a problem with your heart (valve disorder, a disturbance of the cardiac rhythm)

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 left 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
- severe pain in the abdomen (known as acute abdomen)

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 risk 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 seven pill-free days). If this bleeding occurs for more than a few months, or if it begins after some months, contact your doctor as they must find out if anything is wrong.

What to do if no bleeding occurs during the seven pill-free days

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. Only start the next strip if you are sure that you are not pregnant.

Yasmin and using other medicines

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 are taking 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. rifampicin)
 - 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.
 - medicines containing ciclosporin
 - the anti-epileptic lamotrigine (this could lead to an increased frequency of seizures)

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

Taking Yasmin with 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 hormonal 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 taking it immediately and contact your doctor. If you want to become pregnant, you can stop taking Yasmin at any time (see also page 10 "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 the use of machines.

Important information about some of the ingredients of Yasmin

Yasmin contains lactose.

If you cannot tolerate certain sugars, contact your doctor before you take Yasmin.

3. HOW TO TAKE YASMIN

Take Yasmin every day for 21 days

Yasmin comes in strips of 21 pills, each marked with a day of the week.

- *Take your pill at the same time every day.*
- *Start by taking a pill marked with the correct day of the week.*
- *Follow the direction of the arrows on the strip. Take one pill each day, until you have finished all 21 pills.*
- *Swallow each pill whole, with water if necessary. Do not chew the pill.*

Then have seven pill-free days

After you have taken all 21 pills in the strip, you have seven days when you take no pills. So, if you take the last pill of one pack on a Friday, you will take the first pill of your next pack on the Saturday of the following week.

Within a few days of taking the last pill from the strip, you should have a withdrawal bleed like a period. This bleed may not have finished when it is time to start your next strip of pills.

You don't need to use extra contraception during these seven pill-free days – as long as you have taken your pills correctly and start the next strip of pills on time.

Then start your next strip

Start taking your next strip of Yasmin after the seven pill-free days – even if you are still bleeding. Always start the new strip on time.

During the seven pill-free days, when you take no tablets, bleeding should begin (so-called withdrawal bleeding). This usually starts on the 2nd or 3rd day after the last tablet of Yasmin. Start the following strip after the last day of the seven pill-free days, whether your bleeding has stopped or not.

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 your 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 finish (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 intrauterine system IUS)*

You may switch any day from the progestogen-only pill (from an implant or an IUS 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 taking Yasmin.

- *After a miscarriage or abortion*

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. This means that you will have contraceptive protection with your first pill.

- *After having a baby*

You can start taking 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 taking Yasmin.

If, after having a baby, you have had sex before starting Yasmin (again), you must first be sure that you are not pregnant or wait until your next period.

- *If you are breast-feeding and want to start Yasmin after having a baby*

Read the section on “Breast-feeding”, page 5.

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

If you take more Yasmin than you should

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 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 also the diagram on page 9):

- ***More than one tablet forgotten in this strip***
Contact your doctor.
- ***One tablet forgotten between days 1 - 7***

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 between days 8 – 14***

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. If you forget more than one tablet use an additional barrier method such as a condom for 7 days.

- ***One tablet forgotten between days 15 - 21***

- *You can choose between two possibilities:*

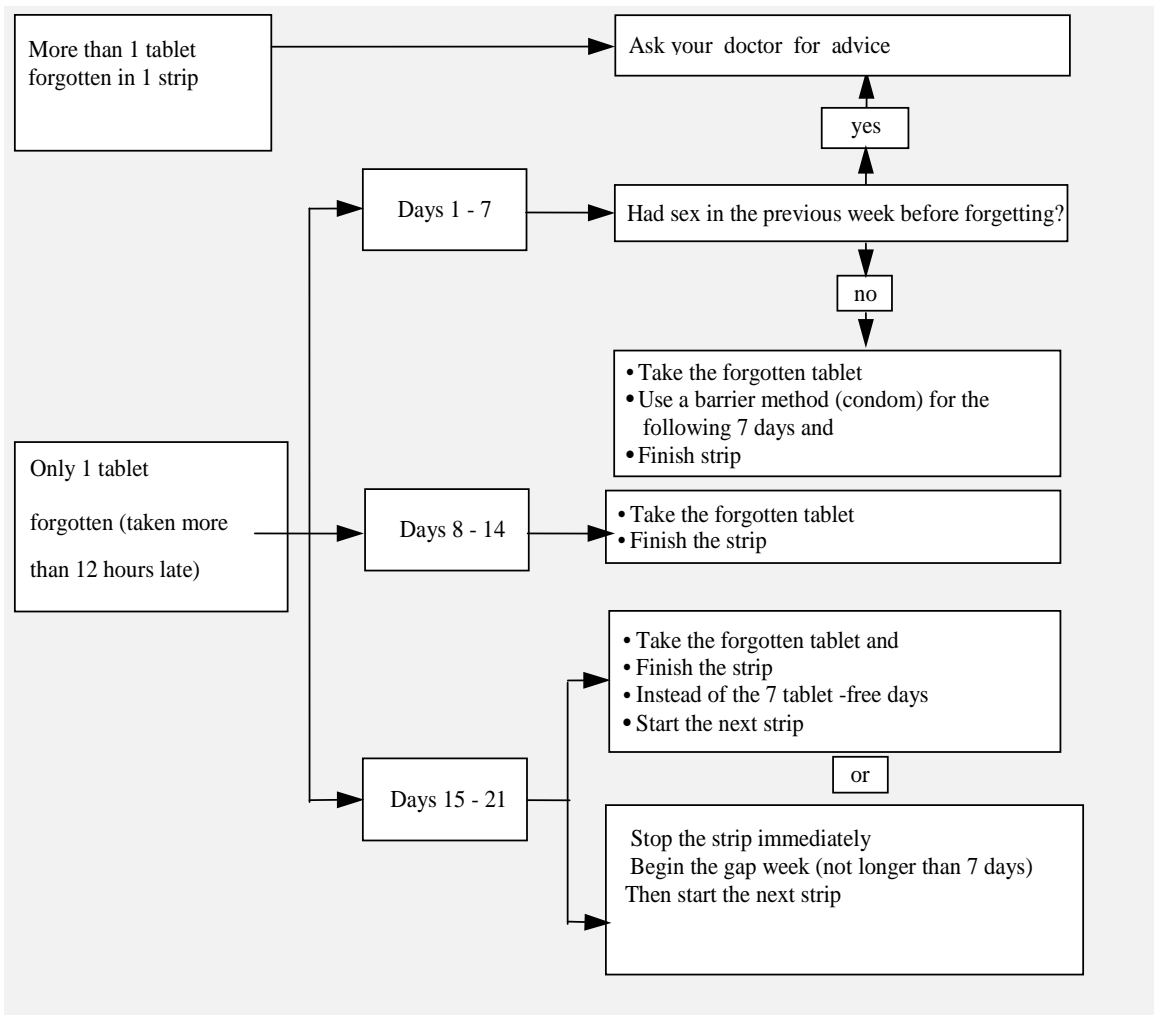
1. *Take the forgotten tablet as soon as you remember, even if that means that you have to take two tablets at the same time. Continue taking the tablets at the usual time. Instead of having seven pill-free days start the next strip as soon as you have taken the last tablet.*

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

2. *You can also stop the tablets and go directly to the tablet-free period (**record the day on which you forgot your tablet**). If you want to start a new strip on the day you always start, make the tablet-free period less than 7 days.*

If you follow 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 tablet-free period, you may be pregnant. Contact your doctor before you start the next strip.*



What to do in the case of vomiting or severe diarrhoea

If you vomit within 3-4 hours of taking a tablet or you have severe diarrhoea, there is a risk that the active substances in the 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, you should follow the advice given under “If you forget to take Yasmin” on page 8.

Delaying your period: what you need to know

Although it is not recommended, you can delay your period by skipping the seven pill-free days and going straight to a new strip of Yasmin and finishing it. You may experience light or menstruation-like bleeding while using this second strip. After the usual pill-free period of 7 days *start your next strip*.

It is advisable to consult 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 seven pill-free days. If you have to change this day, make the pill-free period shorter – (but never longer – 7 days is the maximum!). For example, if you start the seven pill-free days 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 pill-free period very short (for example 3 days or less) you may not have any bleeding during this time. You may then experience light or menstruation-like bleeding.

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

If you want to 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 menstrual 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 product, ask a doctor or pharmacist.

4. POSSIBLE SIDE EFFECTS

Like all medicines, Yasmin 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:

Serious side effects: – see you doctor straight away

Signs of a blood clot:

- a **migraine** for the first time, a migraine that is worse than normal, or unusually frequent or severe **headaches**
- any sudden **changes to your eyesight** (such as loss of vision or blurred vision)
- any sudden **changes to your hearing, speech, sense of smell, taste or touch**
- **pain or swelling in your leg**
- **stabbing pain when you breathe**
- **coughing** for no apparent reason
- **pain and tightness in the chest**
- sudden **weakness** or **numbness** in one side or part of your body
- **dizziness** or **fainting**

Signs of a severe allergic reaction to Yasmin:

- **swelling** of the **face, lips, mouth, tongue or throat**

Signs of breast cancer include:

- **dimpling** of the skin
- **changes in the nipple**
- any **lumps** you can see or feel.

Signs of cancer of the cervix include:

- **vaginal discharge** that smells and/or contains blood
- unusual **vaginal bleeding**
- **pelvic pain**
- **painful sex**

Signs of severe liver problems include:

- severe **pain in your upper abdomen**
- **yellow skin or eyes** (jaundice)
- **inflammation of the liver** (hepatitis)
- your whole body starts **itching**

➤ *If you think you may have any of these, see a doctor straight away. You may need to stop taking Yasmin*

Common side effects (between 1 and 10 in every 100 users may be affected):

- depressive mood
- headache, migraine
- nausea
- breast pain, breast tenderness, menstrual disorders, bleeding between periods, thick whitish vaginal discharge, vaginal yeast infection

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

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

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

- hearing impairment
- asthma
- breast secretion
- blockage of a blood vessel by clot formed elsewhere in the body
- *allergic reactions (hypersensitivity)*
- *the skin conditions erythema nodosum (characterized by painful reddish skin nodules) or erythema multiforme (characterized by rash with target-shaped reddening or sores).*

If any of the side effects gets serious or if you notice any side effects not listed in this booklet or if you think that this may be the case, please tell your doctor or pharmacist.

5. **HOW TO STORE YASMIN**

Keep Yasmin out of the reach and sight of children.

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

Expiry date

Do not take Yasmin after the expiry date which is printed on the pack after "EXP"

The expiry date refers to the last day of that month.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose medicines no longer required. These measures will help to protect the environment.

6. **FURTHER INFORMATION**

What Yasmin contains

- *The active substances are drospirenone and ethinylestradiol. Each active tablet contains 0.030 milligrams ethinylestradiol and 3 milligrams drospirenone.*
- *Other ingredients in the active tablets are lactose monohydrate, maize starch, pregelatinised maize starch, povidone K25, magnesium stearate (E470b), hypromellose (E464), macrogol 6000, talc (E553b), titanium dioxide (E171) and iron oxide yellow (E172).*

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, and 6 blisters each with 21 tablets.*

Not all pack sizes may be marketed.

Marketing Authorisation Holder

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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, Netherlands, Norway, Portugal, Spain, Sweden, United Kingdom: **Yasmin**
- France: **Jasmine**

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