

The medicine is dispensed with a doctor's prescription only



Each orange tablet contains: drospirenone 3 mg ethinylestradiol (as betadex clathrate) 0.03 mg levomefolate calcium 0.451 mg

Each light-orange tablet contains: levomefolate calcium 0.451 mg

Inactive ingredients and allergens: See section 6 "Additional information" and section 2 "Important information regarding some of the ingredients of the medicine".

Read the entire leaflet carefully before using this medicine. This leaflet contains concise information about this medicine. If you have any further questions, consult your doctor or pharmacist.

This medicine has been prescribed for you to prevent pregnancy. Do not pass it on to others. It may harm them even if it seems to you that the purpose of use is similar.

- Essential information about the medicine**
- Do not use Yasmin Plus if you smoke and are over 35 years of age. Taking birth control pills while smoking increases your risk of developing serious cardiac side effects (cardiovascular problems), including death due to heart attack, blood clots or stroke. This risk increases with age and the number of cigarettes you smoke.
 - Birth control pills lower the chance of becoming pregnant if taken according to the instructions. They do not protect against contraction of HIV (AIDS) or any other sexually transmitted disease.

1) What is this medicine intended for?

Yasmin Plus is intended to prevent pregnancy and also as a folate supplement in women who chose to use a birth control pill.

Therapeutic group: Yasmin Plus belongs to a group of medicines called birth control pills. Yasmin Plus contains 2 types of female hormones: synthetic estrogen (ethinylestradiol) and progestin (drospirenone), and also contains levomefolate calcium, which belongs to the B vitamin group (folate).

It is recommended that women of childbearing age take 0.4 mg (400 mcg) of folic acid every day to reduce the risk of pregnancy in which the unborn baby will suffer from a rare defect (open neural tube defect). The amount of folate in Yasmin Plus tablets serves as a supplement to folate in the diet, thus reducing this risk, if you become pregnant while taking the medicine or immediately after discontinuing it.

2) Before using this medicine
Do not use this medicine if:

- You are sensitive (allergic) to drospirenone, ethinylestradiol, or levomefolate calcium or to any of the other ingredients contained in the medicine. For the list of inactive ingredients, see section 6 "Additional Information".
- You have ever suffered from blood clots in your legs (deep vein thrombosis), lungs (pulmonary embolism), or eyes (retinal thrombosis).
- You have ever had a stroke.
- You have ever had a heart attack.
- You are suffering from certain heart valve problems or irregular heart rate that may cause development of blood clots in the heart.
- You are suffering from an inherited blood clotting problem causing the blood to clot more than normal.
- You are suffering from high blood pressure that is not controlled by medicines.
- You are suffering from diabetes accompanied by kidney, eye, nerve, or blood vessel damage.
- You have ever suffered from certain kinds of severe migraine with aura, numbness, weakness or changes in vision.
- You are suffering from an undiagnosed abnormal uterine bleeding.
- You have ever suffered from breast cancer or any other cancer that is sensitive to female hormones.
- You are taking a drug combination for hepatitis C treatment containing ombitasvir/paritaprevir/ritonavir, with or without dasabuvir. Taking such combination may lead to elevated blood level of the liver enzyme alanine aminotransferase (ALT).
- You are suffering from a liver disease, including liver tumors.
- You are suffering from a kidney disease.
- You are suffering from an adrenal gland disease.
- You smoke and are over 35 years of age.
- You are pregnant or suspect you are pregnant.

Use of birth control pills may not be a suitable choice for you if you have ever had jaundice (yellowing of the skin or eyes) that developed during pregnancy (this condition is also called cholestasis of pregnancy).

Tell the doctor if you are suffering, or have suffered in the past, from any of the above-mentioned conditions (the doctor can recommend an alternative method of contraception for you).

Tell the doctor if you are already taking folate supplements.

Special warnings about using this medicine

- Birth control pills do not protect against contracting sexually transmitted disease, including HIV, the virus causing AIDS.
- Do not skip any tablets, even if you do not have sex very often.
- The chance of becoming pregnant depends on whether you consistently take the tablets as per the instructions detailed below. The more you ensure taking the tablets as instructed, the lower the chance that you will become pregnant. Based on data of 2 studies, about 1 woman in 100 can become pregnant during the first year of using Yasmin Plus.
- If you miss a period, you may be pregnant. However, some women taking birth control pills miss a period or have light period, even when they are not pregnant. Consult the doctor if you:
 - suspect that you are pregnant
 - missed one period and have not regularly taken the birth control pill every day
 - missed 2 periods in a row
- Many women experience spotting, irregular light bleeding between periods or nausea when using the first 1-3 packs.
- If spotting, light bleeding between periods or nausea occur, do not stop taking the tablets. The effect will usually disappear. If these effects persist, contact the doctor for advice.
- Due to the increased risk of blood clot formation, you must stop taking Yasmin Plus at least 4 weeks before undergoing major surgery. Do not resume use before at least 2 weeks from the surgery have elapsed.
- The progestin drospirenone may increase potassium levels, therefore, do not use Yasmin Plus if you have a kidney, liver, or adrenal disease since use of Yasmin Plus may cause severe heart and health problems (see section "Do not use this medicine if"). Taking certain medicines may also increase the potassium level (see section "Drug interactions").

What are the most serious risks when taking birth control pills?

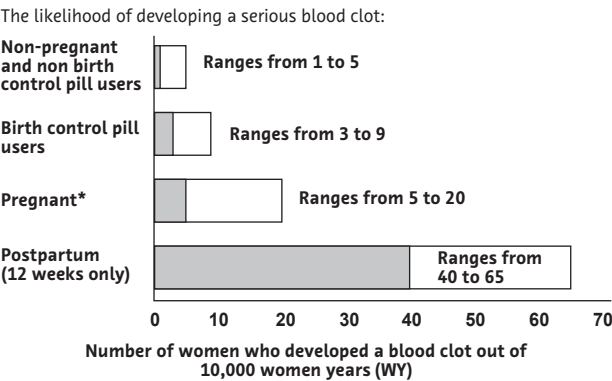
Like pregnancy, birth control pills increase the risk of developing a serious blood clot (see the graph further on in the leaflet), especially in women who have other risk factors, such as smoking, obesity, or who are over 35 years of age. The risk is higher when you first start taking birth control pills or when you restart the same pill or another type of birth control pill after a break of one month or more. Women who take birth control pills that contain drospirenone (such as Yasmin Plus) may be at a higher risk of developing a blood clot. Some studies have indicated that the risk of developing blood clots was higher for women who took birth control pills that contained drospirenone than for women who took birth control pills that did not contain drospirenone.

Talk with the doctor about the risk of developing a blood clot before deciding which contraceptive is suitable for you.

Blood clot, if causing conditions such as a heart attack or stroke, may lead to permanent disability and even to death. Examples of serious blood clots are blood clots that occur in the:

- legs (deep vein thrombosis)
- lungs (pulmonary embolism)
- eyes (loss of eyesight)
- heart (heart attack)
- brain (stroke)

The risk of developing a blood clot can be described as follows:
If 10,000 women who are not pregnant and do not use birth control pills are followed for one year, between 1 and 5 would develop a blood clot.
The following graph shows the likelihood of developing a serious blood clot for women who are not pregnant and do not use birth control pills, for women who use birth control pills, for pregnant women, and for women in the first 12 weeks after giving birth.



A small number of women who take birth control pills may develop:

- Hypertension
- Gallbladder problems
- Rare malignant or benign liver tumors

All of the above-mentioned effects are uncommon in healthy women.

Do birth control pills cause cancer?

Taking birth control pills does not seem to cause breast cancer. However, if you have breast cancer, or have had it in the past, do not use birth control pills since there are certain types of cancer that are sensitive to hormones. Women who take birth control pills are at a slightly higher risk of developing cervical cancer. However, this risk may be due to other reasons such as having multiple sexual partners.

Changes in menstrual bleeding when taking Yasmin Plus

Irregular vaginal bleeding or spotting may occur when using Yasmin Plus. Irregular bleeding may vary from slight staining between menstrual periods to breakthrough bleeding, at a volume that resembles that of menstrual bleeding. Irregular bleeding occurs most often during the first few months of using birth control pills, but may also occur after longer use. Such bleeding may be temporary and in most cases does not indicate any serious problems. It is important to take the tablets on time. If the bleeding occurs during more than one month, or is unusually heavy, or lasts for more than a few days, contact the doctor immediately.

Some women do not get a period; this should not be a cause for concern as long as the tablets were taken as instructed.

When menstrual bleeding does not occur

It is not uncommon to miss menstrual bleeding. However, if you miss 2 periods in a row or miss one period when you have not taken the birth control pills regularly, contact your doctor. Tell the doctor if you feel signs of pregnancy such as morning sickness or unusual breast tenderness. It is important that your doctor checks if you are pregnant. Stop taking Yasmin Plus if you are pregnant.

Smoking

Do not use Yasmin Plus if you smoke and are over 35 years of age. Taking birth control pills while smoking increases your risk of developing severe cardiac side effects (cardiovascular problems), including death due to a heart attack, blood clots or stroke. This risk increases with age and the number of cigarettes you smoke.

Tests and follow-up

If you have to perform a blood test, inform the doctor or laboratory staff that you are taking birth control pills. Certain blood test results may be affected by birth control pills.

- Drug interactions**
- If you are taking, or have recently taken, other medicines, including non-prescription medicines and nutritional supplements, tell the doctor or pharmacist.** In particular, if you are taking:
- Medicines which may increase potassium levels:
 - Nonsteroidal anti-inflammatory drugs (e.g., ibuprofen, naproxen), for daily long-term treatment of arthritis or other problems
 - Potassium-sparing diuretics (e.g., spironolactone)
 - Potassium supplements
 - Angiotensin-converting enzyme inhibitors (e.g., captopril, enalapril, lisinopril)
 - Angiotensin-II receptor antagonists (e.g., losartan, valsartan, irbesartan)
 - Heparin
 - Aldosterone receptor antagonists
- If you are using these medicines on a daily basis and for long-term treatment, consult your doctor to determine whether Yasmin Plus is suitable for you, and it is recommended that a blood test be performed to determine blood potassium levels during the first month of taking Yasmin Plus.
- Medicines which may impair the efficacy of birth control pills and/or cause unexpected bleeding such as:
 - Phenytin
 - Barbiturates
 - Carbamazepine
 - Bosentan
 - Felbamate
 - Griseofulvin
 - Oxcarbazepine
 - Rifampin
 - Topiramate
 - The herbal preparation Hypericum (St. John's wort)
- Consider using an alternative contraception method if you are taking any of the aforementioned medicines which may impair the efficacy of birth control pills.
- Medicines which may increase the blood levels of hormones contained in birth control pills, such as:
 - Atorvastatin
 - Ascorbic acid
 - Paracetamol/acetaminophen
 - Antifungals (such as ketoconazole, itraconazole, voriconazole, fluconazole)
 - Verapamil
 - Macrolide antibiotics (such as clarithromycin, erythromycin)
 - Diltiazem
 - Grapefruit juice
 - Medicines which may increase or reduce the blood levels of hormones contained in birth control pills, such as:
 - Protease inhibitors and non-nucleoside reverse transcriptase inhibitors for treatment of HIV and hepatitis C infections. Do not use Yasmin Plus if you are taking a drug combination for hepatitis C treatment containing ombitasvir/paritaprevir/ritonavir, with or without dasabuvir. Taking such combination may lead to elevated blood level of the liver enzyme alanine aminotransferase (ALT).
 - Medicines, the efficacy of which, may be impaired when used simultaneously with birth control pills:
 - Lamotrigine for treatment of epilepsy. Co-administration of birth control pills and lamotrigine may increase the risk of seizures; therefore, the dosage of lamotrigine may need to be adjusted by the doctor.
 - Medicines for thyroid hormone replacement therapy – it is recommended to consult a doctor if you are taking medicines for thyroid hormone replacement therapy.
 - Medicines, the blood levels of which, may be affected by using Yasmin Plus:
 - Theophylline for treatment of respiratory problems
 - Tizanidine for treatment of muscle pain and/or muscle cramps
 - Omeprazole for treatment of stomach problems
 - Voriconazole

Folates may reduce the efficacy of certain medicines, including medicines for treatment of epilepsy; therefore, it is recommended to consult the doctor if you are taking medicines such as:

- Medicines, the efficacy of which, may be impaired when used simultaneously with folates:
 - Medicines for treatment of epilepsy (such as phenytoin)
 - Methotrexate
 - Pyrimethamine
- Medicines which may affect the levels of folate in blood, such as:
 - Methotrexate
 - Sulfasalazine
 - Cholestyramine
- Medicines for treatment of epilepsy such as carbamazepine, phenytoin, phenobarbital, primidone and valproic acid

Use of the medicine and food

The medicine can be swallowed regardless of meals (on an empty stomach or with food).

Pregnancy, breastfeeding and fertility

Do not take birth control pills if you are pregnant. Nevertheless, birth control pills taken by accident during pregnancy are not known to cause congenital defects in an unborn baby.

If you are breastfeeding, consider using another kind of contraceptive method until you decide to stop breastfeeding. Birth control pills containing estrogen, such as Yasmin Plus, may reduce the production of breast milk. Small amounts of the hormones contained in the pill pass into breast milk.

Important information regarding some of the ingredients of the medicine

The medicine contains lactose.

If you have been told by your doctor that you have an intolerance to certain sugars, contact the doctor before commencing treatment with the medicine.

3) How to use this medicine?

Always use the medicine according to the doctor's instructions. Check with the doctor or pharmacist if you are not sure about your dose or about how to use this medicine.

- The dosage and treatment regimen will be determined by the doctor only. The usual dosage is generally one tablet, every day, at the same time, for 28 days.

Do not exceed the recommended dose.

Swallow the tablet whole, with water, if necessary.

Do not crush/split/chew the tablet so as not to damage its coating and due to the concern that the dosage will not be precise.

- Before you start taking the tablets

- Decide what time of day you want to take the tablet.
It is important to take Yasmin Plus at the same time every day in the order indicated on the package, preferably after the evening meal or at bedtime, with water, as needed. You can take Yasmin Plus regardless of meals.
- Look at the pack of tablets - it contains 28 tablets.
The Yasmin Plus pack contains 21 orange tablets (which contain hormones and folate) to be taken for 3 weeks, followed by 7 light-orange tablets (that do not contain hormones, but contain folate), to be taken for 1 week. It is important to take the light-orange tablets, since they contain folate.
- Also look for:
 - The marking on the pack that indicates where to start taking the tablets.
 - The correct order for taking the tablets (in the direction of the arrows).
- Be sure to always have (a) another kind of contraceptive (such as a condom and spermicide) to use as a back-up in case you forget to take a tablet, and (b) an extra new pack of Yasmin Plus.

- When to start the first pack of tablets
You can choose the day to start taking tablets from your first pack of tablets. Decide with the doctor which is the most suitable day for you. Pick a dosing time which will be easy for you to remember.

- Starting on "Day 1":
 - Take the first orange tablet of the pack during the first 24 hours of your menstrual bleeding.
 - You will not need to use an additional contraceptive method as a back-up, since you are starting to take the tablets at the beginning of your menstrual bleeding. However, if you start taking Yasmin Plus later than the first day of your menstrual bleeding, it is recommended to use an additional contraceptive method (such as a condom and spermicide) as a back-up until you have completed taking 7 orange tablets.
- Starting on Sunday:
 - Take the first orange tablet of the pack on the Sunday after your menstrual bleeding starts, even if you are still bleeding. If your bleeding begins on Sunday, start the pack that same day.
 - Use an additional contraceptive method (such as a condom and spermicide) as a back-up if you have sex anytime from the Sunday you started using the first pack and the next Sunday (7 days). This also applies if you start taking Yasmin Plus after having been pregnant, and you have not yet had a menstrual bleeding since your pregnancy.

- When switching from another birth control pill
When switching from another birth control pill, start taking Yasmin Plus on the same day you would have started a new pack of the previous birth control pill.
- When switching from another type of contraceptive method
When switching from a transdermal patch or vaginal ring, start taking Yasmin Plus on the same day when the next application or placement would have been due. When switching from an injection, start taking Yasmin Plus on the same day when the next injection would have been due. When switching from an intrauterine device or an implant, start taking Yasmin Plus on the day of the intrauterine device or implant removal.

- What to do during the month
 - Take one tablet at the same time every day until the pack is finished.
Do not skip tablets even if you have spotting or breakthrough bleeding or if you feel nauseous.
 - When you finish a pack, start a new pack on the day after taking the last light-orange tablet. It is important to take the light-orange tablets since they contain folate. Do not wait between finishing one pack and starting a new pack.

If you have accidentally taken a higher dose

There have been no reports of severe side effects resulting from overdose of birth control pills, even if accidentally taken by children.

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

If you forget to take the medicine

If you forgot to take the medicine or if you started a pack late, you may become pregnant. The possibility of becoming pregnant increases with the number of missed tablets. If you forgot to take tablets, see the instructions below.

If you forget to take tablets, spotting or light bleeding may occur, even if you have taken the missed tablets.

You may experience nausea on the days on which you take 2 tablets to compensate for missed tablets.

If you experience difficulties remembering to take the tablets on time, consult the doctor about how to help you remember or about using another contraceptive method.

If you miss one orange tablet of your pack:

- Take the tablet as soon as you remember. Take the next tablet at the regular time. This means you may take 2 tablets in one day.
- There is no need to use an additional contraceptive method if you have sex.

If you miss 2 orange tablets in a row in Week 1 or Week 2 of your pack:

- Take 2 tablets on the day you remember and 2 tablets the next day.
- Then, take one tablet a day until you finish the pack.
- There is a chance you will become pregnant if you had sex in the 7 days since you started taking the tablets again. Use an additional contraceptive method (such as a condom and spermicide) as a back-up for those 7 days.

If you miss 2 orange tablets in a row in Week 3 of your pack:

- If you started the pack on "Day 1" (the first 24 hours of your menstrual bleeding):
Throw out the rest of the tablets in the pack and start taking tablets from a new pack that same day.
- If you started the pack on a Sunday:
Keep taking one tablet every day until Sunday. On Sunday, throw out the rest of the tablets in the pack and start taking tablets from a new pack that same day.
- There is a chance you will become pregnant if you had sex in the 7 days since you started taking the tablets again. Use an additional contraceptive method (such as a condom and spermicide) as a back-up for those 7 days.

Registration holder's name and address: Bayer Israel Ltd., 36 Hacharash St., Hod Hasharon 4527702.

Manufacturer's name and address: Bayer A.G., Berlin, Germany.

- Revised in August 2020.
- Registration number of the medicine in the National Drug Registry of the Ministry of Health: 152-83-33906-00

- If you miss 3 or more orange tablets in a row in any week:**
- If you started the pack on "Day 1" (the first 24 hours of your menstrual bleeding):
Throw out the rest of the tablets in the pack and start taking tablets from a new pack that same day.
 - If you started the pack on a Sunday:
Keep taking one tablet every day until Sunday. On Sunday, throw out the rest of the tablets in the pack and start taking tablets from a new pack that same day.
 - There is a chance that you will become pregnant if you had sex in the 7 days since you started taking the tablets again. Use an additional contraceptive method (such as a condom and spermicide) as a back-up for those 7 days.
 - You may not have your period that month, but this is expected. However, if you miss 2 periods in a row, contact your doctor because you might be pregnant.

If you miss one or more of the 7 light-orange tablets in Week 4:

Throw away the tablets you missed.

Keep taking one tablet each day until you finish the pack.

There is no need to use an additional contraceptive method as a back-up.

If you are still not sure what to do about tablets you have missed during the month:

Use an additional contraceptive method as a back-up (such as a condom and spermicide) any time you have sex.

Contact the doctor and continue taking one active orange tablet each day until you receive other instructions from the doctor.

What you should do if you experience vomiting or diarrhea

If you are vomiting within 3-4 hours of taking the tablet, follow the instructions in section 3 "If you forget to take the medicine". If you are vomiting or have diarrhea, your birth control pill may not work as well. Use an additional contraceptive method such as a condom and spermicide, until you consult your doctor.

In addition, if you have diarrhea or are concomitantly taking other medicines, including certain antibiotics and herbal preparations, such as the herbal preparation Hypericum (St. John's wort), the tablets may not work with maximal efficacy. Use an additional contraceptive method (such as a condom and spermicide) as a back-up until you consult the doctor.

What you should do if you want to become pregnant

You may stop taking the tablets whenever you wish. Consider an appointment with your doctor for a pre-pregnancy checkup before you stop taking birth control pills. Talk with your doctor about taking an appropriate folate supplement if you stop taking Yasmin Plus, or if you are pregnant, or if you are planning to become pregnant.

Adhere to the treatment as recommended by your doctor.

If you stop taking the medicine

Before stopping, talk to your doctor about the consequences.

- Do not take medicines in the dark! Check the label and dose every time you take a medicine. Wear glasses if you need them.**

If you have any further questions about using this medicine, consult your doctor or pharmacist.

4) Side effects

Like with all medicines, using Yasmin Plus may cause side effects in some users. Do not be alarmed by this list of side effects; you may not experience any of them.

Serious side effects

Use of birth control pills may increase the risk of a severe blood clot and liver diseases. Additional information regarding serious risks resulting from taking birth control pills are detailed in section 2 "What are the most serious risks when taking birth control pills?", "Do birth control pills cause cancer?".

Additional serious side effects:
Depression, pulmonary embolism, skin reactions and uterine fibroid.

Contact a doctor immediately if you experience any of the following effects:

- Persistent leg pain
- Sudden shortness of breath
- Sudden vision loss, partial or complete
- Severe pain in the chest
- Sudden, severe and unusual headache
- Weakness or numbness in an arm or leg, or difficulty speaking
- Yellowing of the skin or whites of the eye

Additional side effects

Common side effects

- Spotting or breakthrough bleeding
- Nausea, vomiting, abdominal pain or discomfort
- Breast tenderness or pain
- Headache or migraine
- Mood changes
- Premenstrual syndrome

These side effects are usually mild and resolve with time.

Less common side effects

- Acne
- Reduced sexual desire
- Bloating or fluid retention
- Dark patches on the skin, especially on the face
- High blood sugar levels, especially in women who have diabetes
- High fat (cholesterol, triglycerides) levels in the blood
- Depression, especially if you have suffered from depression in the past.

Contact a doctor immediately if you have any thoughts of harming yourself

- Intolerance to contact lenses
- Body weight changes

Post-marketing information:

The following side effects have been observed during post-marketing use of another birth control pill containing the same hormones as Yasmin Plus. It is impossible to estimate their frequency or determine whether they result from use of the medicine:

- Effects associated with vascular disorders: venous and arterial thromboembolic events (including pulmonary embolism, deep vein thrombosis, intracardiac thrombosis, intracranial or cerebral venous thrombosis, retinal vein thrombosis, myocardial infarction and stroke), hypertension
- Effects associated with hepatobiliary disorders: gallbladder disease
- Effects associated with immune system disorders: hypersensitivity
- Effects associated with metabolism and nutrition disorders: hyperkalemia
- Effects associated with skin and subcutaneous tissue disorders: chloasma

This is not a complete list of side effects.

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.

You can report side effects to the Ministry of Health by following the link 'Reporting Side Effects of Drug Treatment' on the Ministry of Health home page (www.health.gov.il) which links to an online form for reporting side effects. You can also use this link: <https://sideeffects.health.gov.il>

- 5) How to store the medicine?**
- Avoid poisoning! To avoid poisoning, keep this, and all other medicines, in a closed place, out of the reach and sight of children and/or infants. Do not induce vomiting unless explicitly instructed to do so by a doctor.
 - Do not use the medicine after the expiry date (exp. date) which is stated on the package. The expiry date refers to the last day of that month.
 - Do not store at a temperature above 25°C.

6) Additional information

In addition to the active ingredients, this medicine also contains inactive ingredients. Each orange tablet contains the following inactive ingredients:
Lactose monohydrate, Cellulose microcrystalline, Croscarmellose sodium, Hydroxypropylcellulose 5 cP, Magnesium stearate, Lacquer orange or alternatively: Hypromellose 5 cP, Macrogol 6000, Talc, Titanium dioxide, Ferric oxide yellow, Ferric oxide red

Each light-orange tablet contains the following inactive ingredients:
Lactose monohydrate, Cellulose microcrystalline, Croscarmellose sodium, Hydroxypropylcellulose 5 cP, Magnesium stearate, Lacquer light orange or alternatively: Hypromellose 5 cP, Macrogol 6000, Talc, Titanium dioxide, Ferric oxide red, Ferric oxide yellow

Each orange tablet contains 45.32 mg lactose monohydrate.
Each light-orange tablet contains 48.35 mg lactose monohydrate.

- What the medicine looks like and the contents of the pack**
Each Yasmin Plus pack contains 21 orange and 7 light-orange tablets. The orange tablets are film-coated, round and biconvex. The symbol "Y+" is imprinted within a hexagon on one side.
The light-orange tablets are film-coated, round and biconvex. The symbol "M+" is imprinted within a hexagon on one side.
The tablets are provided in blister packs of 1x28, 3x28, 6x28 tablets.
Not all pack sizes may be marketed.