

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

The medicine is dispensed with a doctor's prescription only

Yaz

Film-coated Tablets

Each pink tablet contains:

Drospirenone 3 mg

Ethinylestradiol (as betadex clathrate) 0.02 mg

The white tablets do not contain active ingredients.

Inactive ingredients and allergens: see section 6 "Further Information".

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

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

ESSENTIAL INFORMATION ABOUT COMBINED HORMONAL CONTRACEPTIVES AND ABOUT THE MEDICINE

- When used properly, combined hormonal contraceptives are considered one of the most reliable reversible methods of contraception.
- They slightly increase the risk of a blood clot in the veins and arteries, especially in the first year or when resuming treatment with a combined hormonal contraceptive following a break of 4 or more weeks.
- You must be alert and refer to the doctor if you think you have symptoms of a blood clot (see “Blood clots” in section 2).

1) WHAT IS THE MEDICINE INTENDED FOR?

Yaz is intended to prevent pregnancy and to treat moderate acne and severe premenstrual symptoms, in women who choose to use an oral contraceptive pill.

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

2) BEFORE USING THE MEDICINE

Do not use the preparation if:

- you are sensitive (allergic) to drospirenone or ethinylestradiol or to any of the other ingredients contained in the medicine. An allergic reaction may cause itching, rash, or swelling. For the list of inactive ingredients, see section 6 “Further Information”.

- you are suffering, or have suffered in the past, from a blood clot in the blood vessels of your legs (deep vein thrombosis, DVT), in the lungs (pulmonary embolism, PE), or in other organs of the body.
- you know you have a blood clotting disorder (for instance, protein C deficiency, protein S deficiency, antithrombin III deficiency, Factor V Leiden or antiphospholipid syndrome).
- you have to undergo surgery or if you are immobile for a long time (see “Blood clots” in section 2).
- you have had a heart attack or stroke in the past.
- you have, or have ever had, angina pectoris (a condition that causes severe chest pain and may be a first sign of a heart attack) or transient ischemic attack (TIA – temporary stroke symptoms).
- you have any of the following diseases that may increase your risk of a blood clot in the arteries:
 - severe diabetes with blood vessel damage
 - very high blood pressure
 - very high blood fat levels (cholesterol or triglycerides)
 - a medical condition characterized by high blood levels of homocysteine (hyperhomocysteinemia)
- you are suffering, or have suffered in the past, from a type of migraine called “migraine with aura”.

- you have, or have had, a liver disease, and your liver functions are not yet back to normal.
- you have impaired kidney function (kidney failure).
- you have, or have ever had, a liver tumor.
- you have, or have ever had, or there is suspicion for presence of breast cancer or cancer of the reproductive organs.
- you are suffering from unexplained vaginal bleeding.

If you are suffering from one of the above-mentioned conditions, stop treatment and inform the doctor. The doctor will discuss with you other contraceptive methods that will better suit you.

Special warnings regarding use of the medicine

- Before you start taking Yaz, read the information regarding blood clots further in this section. It is especially important that you read about the symptoms of a blood clot detailed later in section 2 “Blood clots”.
- This leaflet details a number of cases in which you must stop taking Yaz, or cases in which the effectiveness of Yaz may be reduced. In such cases, avoid sexual intercourse or use additional, non-hormonal contraceptive measures, such as use of a condom or any other barrier method. Do not rely on the “safe days” or body temperature measurement methods. These methods may be unreliable, since Yaz affects the cyclic changes in body temperature and in cervical secretions.

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

When should you contact the doctor?

Urgently seek medical attention

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

- While taking Yaz or any other combination pill, some situations may require special care, in which you will have to be regularly checked by your doctor.

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

- if a close relative has or has ever had breast cancer
- if you have a disease of the liver or the gallbladder
- if you have diabetes
- if you suffer from depression

- if you have Crohn's disease or ulcerative colitis (chronic inflammatory bowel disease)
- if you have systemic lupus erythematosus (lupus – a disease that affects the immune system)
- if you have hemolytic uremic syndrome (a blood clotting disorder causing kidney failure)
- if you have sickle cell anemia (an inherited disease of the red blood cells)
- if you have elevated fat levels in the blood (hypertriglyceridemia) or a family history of this condition. Hypertriglyceridemia has been associated with an increased risk of developing pancreatitis
- if you need to undergo surgery, or if you are immobile for a long time (see “Blood clots” in section 2)
- if you have recently given birth, you are at an increased risk of blood clots. Consult your doctor regarding how soon after delivery you can start taking Yaz
- if you have an inflammation in the veins under the skin (superficial thrombophlebitis)
- if you have varicose veins
- if you have epilepsy (see “If you are taking, or have recently taken, other medicines, including non-prescription medicines and nutritional supplements” in section 2)
- if you have a disease that first appeared during pregnancy or earlier use of sex hormones (for example, hearing loss, a blood disease called porphyria, skin rash with blisters during pregnancy [gestational herpes], a nerve disease causing sudden movements of the body [Sydenham's chorea])

- if you have or have ever had goldish-brown patches on the skin (chloasma), known as “pregnancy patches”, especially on the face. If so, avoid exposure to direct sunlight or ultraviolet light
- if you have hereditary angioedema, estrogen-containing preparations may cause the symptoms of the disease or make them worse. Refer to a doctor immediately if you experience symptoms of angioedema such as swollen face, tongue and/or throat and/or difficulty swallowing or hives (urticaria), together with breathing difficulties

■ Blood clots

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

The risk level of thrombosis may vary in accordance with the type of pill you are taking. Consult the doctor regarding the various options.

Blood clots may form:

- in the veins (a condition called “venous thrombosis”, “venous thromboembolism” or VTE)
- in the arteries (a condition called “arterial thrombosis”, “arterial thromboembolism” or ATE)

Recovery from blood clots is not always complete. Rarely, there may be serious lasting effects or, very rarely, there may be life-threatening conditions.

It is important to remember that the overall risk of a harmful blood clot due to use of Yaz is small.

How to recognize a blood clot

Urgently seek medical attention if you notice any of the following signs or symptoms.

Are you experiencing any of these signs?	What are you possibly suffering from?
<ul style="list-style-type: none">• swelling of one of the legs or along a vein in the leg or foot, especially when accompanied by:<ul style="list-style-type: none">◦ pain or tenderness in the leg, which may be felt only when standing or walking◦ increased warmth in the affected leg◦ change in color of the skin of the leg, e.g., turning pale, red or blue	Deep vein thrombosis

Are you experiencing any of these signs?	What are you possibly suffering from?
<ul style="list-style-type: none"> • sudden unexplained breathlessness or rapid breathing • sudden cough without an obvious cause, which may bring up blood • sharp chest pain which increases with deep breathing • severe light-headedness or dizziness • rapid or irregular heartbeat • severe stomach pain <p>If you are unsure, talk to the doctor, as some of these symptoms, such as coughing or breathlessness, may be mistaken for milder conditions such as a respiratory tract infection (e.g., a common cold).</p>	Pulmonary embolism
<p>Symptoms, which usually occur in one eye:</p> <ul style="list-style-type: none"> • sudden loss of vision or • painless blurring of vision, which can progress to loss of vision 	Retinal vein thrombosis (blood clot in the eye)

Are you experiencing any of these signs?	What are you possibly suffering from?
<ul style="list-style-type: none">• chest pain, discomfort, pressure, or heaviness• sensation of squeezing or fullness in the chest, arm or below the breastbone• feeling of fullness, choking or indigestion• upper body discomfort radiating to the back, jaw, throat, arm and stomach• sweating, nausea, vomiting or dizziness• extreme weakness, anxiety, or shortness of breath• rapid or irregular heartbeat	Heart attack

Are you experiencing any of these signs?	What are you possibly suffering from?
<ul style="list-style-type: none"> • sudden weakness or numbness of the face, arm or leg, especially on one side of the body • sudden confusion, trouble speaking or understanding • sudden trouble seeing in one or both eyes • sudden trouble walking, dizziness, loss of balance or coordination • sudden, severe or prolonged headache with no known cause • loss of consciousness or fainting with or without seizure <p>Sometimes, the symptoms of stroke can be brief, with an almost immediate and full recovery, but you must still immediately seek medical attention, as you may be at risk of another stroke.</p>	Stroke
<ul style="list-style-type: none"> • swelling and slight blue discoloration of the extremities • severe stomach pain 	Blood clots blocking other blood vessels

Blood clots in a vein

What can happen if a blood clot forms in a vein?

- The use of combined hormonal contraceptives has been associated with an increase in the risk of blood clots in the vein (venous thrombosis). However, these side effects are rare and most frequently occur in the first year of use of a combined hormonal contraceptive.
- If a blood clot forms in a vein in the leg or foot, it can cause a deep vein thrombosis (DVT).
- If a blood clot travels from the leg and reaches the lung, it can cause a pulmonary embolism.
- Rarely, a blood clot may form in a vein in another organ such as the eye (retinal vein thrombosis).

When is the risk of developing a blood clot in a vein highest?

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

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

When you stop using Yaz, your risk of developing a blood clot returns to normal within a few weeks.

What is the risk of developing a blood clot?

The risk depends on your natural risk of venous thromboembolism (VTE) and the type of combined hormonal contraceptive you are taking. Use of pills containing drospirenone (such as Yaz) may carry an increased risk of developing a blood clot.

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

- Out of 10,000 women who are not using any combined hormonal contraceptive and are not pregnant, about 2 will develop a blood clot in a year.
- Out of 10,000 women who are using a combined hormonal contraceptive that contains levonorgestrel, norethisterone, or norgestimate, about 5-7 will develop a blood clot in a year.
- Out of 10,000 women who are using a combined hormonal contraceptive that contains drospirenone, such as Yaz, between about 9 to 12 women will develop a blood clot in a year.
- The risk of developing a blood clot will vary according to your personal medical history (see “Factors that increase your risk of a blood clot in a vein/an artery” in section 2).

	Risk of developing a blood clot in a year
Women who are not using a combined hormonal pill and are not pregnant	About 2 out of 10,000 women
Women using a combined hormonal contraceptive pill containing levonorgestrel, norethisterone or norgestimate	About 5-7 out of 10,000 women
Women using Yaz	About 9-12 out of 10,000 women

Factors that increase your risk of developing a blood clot in a vein

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

- if you are significantly overweight (BMI over 30 kg/m²).
- if a member of your immediate family has had a blood clot in the leg, lung or other organ at a young age (e.g., below the age of 50). In such a case, you could have a hereditary blood clotting disorder.
- if you need to undergo surgery, or if you are immobile for a long time because of an injury or illness, or you have your leg in a cast. The use of Yaz may need to be stopped several weeks before surgery or during the period in which you are less mobile. If you need to stop Yaz, ask your doctor when you can start using it again.
- with age (particularly above about the age of 35).
- if you gave birth within the past few weeks.

The risk of developing a blood clot increases the more of these conditions you have. Air travel (more than 4 hours) may temporarily increase your risk of a blood clot, particularly if you have some of the other factors listed.

It is important to tell your doctor if any of these conditions applies to you, even if you are unsure. The doctor may decide that you should stop taking Yaz.

If any of the above conditions changes while you are using Yaz, for example, if a close family member experiences a thrombosis for no known reason, or if you gain a lot of weight, tell your doctor.

Blood clots in an artery

What can happen if a blood clot forms in an artery?

Like a blood clot in a vein, a blood clot in an artery can cause serious problems. For example, a blood clot in an artery can cause a heart attack or a stroke.

Factors that increase your risk of developing a blood clot in an artery

It is important to note that the risk of a heart attack or stroke from using Yaz is very low but can increase:

- with age (above the age of about 35)
- if you smoke. When using a combined hormonal contraceptive such as Yaz, it is advisable to stop smoking. If you are unable to stop smoking and are over 35 years of age, your doctor may advise you to use a different type of contraceptive measure
- if you are overweight
- if you have high blood pressure

- if a member of your immediate family has had a heart attack or stroke at a young age (below the age of about 50). In this case, you may also carry an increased risk of having a heart attack or stroke
- if you, or someone in your immediate family, have high blood fat levels (cholesterol or triglycerides)
- if you suffer from migraines, especially “migraine with aura”
- if you have a problem with your heart function (valve disorder, disturbance of the rhythm called atrial fibrillation)
- if you have diabetes.

If you have more than one of these conditions or if one of them is particularly severe, the risk of developing a blood clot may be increased even more.

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

■ Yaz and cancer

Breast cancer has been observed slightly more often in women taking combined oral contraceptive pills, but it is not known whether this increase is caused by the treatment with the pills. For example, it could be that more tumors are detected in women who take combination pills because they are examined more often.

The rate of breast cancer tumors gradually declines after stopping treatment with the combined hormonal contraceptive. It is important to regularly check your breasts and consult the doctor if you feel any lump.

There are rare reports of benign liver tumors, and there are even reports of more isolated cases of malignant liver tumors in patients who took contraceptive pills. Contact the doctor if you have unusually severe abdominal pain.

■ Bleeding between periods

During the first few months of treatment with Yaz, you may have unexpected bleeding (bleeding outside of the days on which you take the white tablets). If this bleeding occurs for more than a few months, or if it begins after a few months of treatment, inform the doctor.

What to do if no bleeding occurs while taking the white tablets

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

If the expected bleeding does not happen over 2 consecutive cycles, you may be pregnant. Contact the doctor immediately. Only start treatment with a new strip if you are sure that you are not pregnant.

■ If you are taking, or have recently taken, other medicines, including non-prescription medicines and nutritional supplements, tell the doctor or pharmacist.

Also inform the dentist or any other doctor who prescribes another medicine for you, that you are taking Yaz. They will be able to advise you if you need to use an additional contraceptive (e.g., condom), and if so, for how long, or, whether the use of the other medicine you need to take should be changed.

It is especially important to inform the doctor or pharmacist if you are taking:

- Certain medicines that can
 - have an influence on the blood levels of Yaz
 - impair the contraceptive efficacy of Yaz
 - cause unexpected bleeding

This includes medicines used for the treatment of:

- epilepsy (e.g., primidone, phenytoin, barbiturates, carbamazepine, oxcarbazepine)
- tuberculosis (e.g., rifampicin)
- AIDS (HIV) and Hepatitis C infections (so-called protease inhibitors and non-nucleoside reverse transcriptase inhibitors such as ritonavir, nevirapine, efavirenz)
- fungal infections (griseofulvin, ketoconazole)
- arthritis, arthrosis (etoricoxib [Arcoxia])
- pulmonary hypertension (bosentan)
- the herbal preparation *Hypericum* (St. John's wort)
- Use of Yaz may influence the effect of other medicines, such as:
 - medicines containing ciclosporin
 - lamotrigine to treat epilepsy (may lead to an increase in the frequency of seizures)
 - theophylline to treat breathing problems
 - tizanidine to treat muscle pain and/or muscle cramps

Use of the medicine and food

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

Pregnancy and breastfeeding

If you are pregnant, you must not take Yaz. If you became pregnant, while using Yaz, you must immediately stop taking Yaz and contact the doctor. If you would like to become pregnant, you can stop taking Yaz at any time (also see “If you stop taking the medicine” in section 3).

It is usually not recommended to take Yaz when breastfeeding. If you want to take the pill while breastfeeding, contact the doctor.

If you are pregnant or breastfeeding, consult the doctor or pharmacist before using the medicine.

Driving and use of machines

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

Smoking

It is recommended that you stop smoking when using a combined hormonal contraceptive such as Yaz. If you cannot stop smoking and you are over the age of 35, your doctor may recommend that you use a different type of contraceptive.

■ Important information regarding some of the ingredients of the medicine

Yaz contains lactose.

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

3) HOW SHOULD YOU USE THE MEDICINE?

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

Each strip contains 24 light pink tablets that contain active ingredients, and 4 white tablets that do not contain active ingredients.

The 2 types of tablets are packaged in a specific, predetermined order. A strip contains 28 tablets.

- The dosage and the treatment regimen will be determined by the doctor only. The usual dosage is generally one tablet every day.

Do not exceed the recommended dose

- Mode of administration

The medicine can be swallowed with a little water.

The medicine can be taken without regard to meal times, but make sure to take the tablet at the same time every day.

Do not crush/halve/chew the tablet, so as not to damage the coating of the tablet.

Be careful not to get confused when taking the tablets: Take the pink tablets for the first 24 days and afterwards, take the white tablets on the following 4 days. Start a new strip immediately after that. Do not take a break between one strip and the next.

Since the tablets have a different composition, it is important to start by taking the tablet in the upper left corner, and to take one tablet every day. To maintain the correct order of administration, follow the direction of the arrows that appear on the back of the strip.

Preparation of the strip before taking the tablets

To help you properly keep track of tablet administration, there are 7 stickers each with the 7 days of the week. Choose the week sticker that starts with the day you begin taking Yaz tablets. For example, if you start taking the tablets on a Wednesday, use the week sticker that starts with “WED”.

Stick the week sticker along the top of the back of the Yaz strip, where it reads “Place week sticker here”, so that the first day is above the tablet marked “1”.

There is now a day indicated above every tablet, so you can see whether you have taken a certain tablet that month. The arrows show the order you are to take the tablets.

During the 4 days when you are taking the white tablets, bleeding, resembling menstrual bleeding, should begin.

The bleeding usually starts on the 2nd or 3rd day after the last pink tablet of Yaz is taken. On the day after you have taken the last white tablet, you should start a new strip, whether your bleeding has stopped or not. This means that you will start each strip on the same day of the week, and bleeding will occur on the same days each month.

Taking Yaz in this manner will also provide protection against pregnancy during the 4 days when you are taking the white tablets.

When can you start using the first strip?

- *If you did not use a hormonal contraceptive in the previous month*
Start taking Yaz tablets on the first day of the menstrual bleeding. In this case, you are immediately protected from pregnancy. You can also begin between days 2-5 of menstrual bleeding, but in this case, an additional contraceptive (e.g., a condom) must be used during the first 7 days of taking Yaz.
- *Switching from another combined oral contraceptive pill, combined (vaginal) ring or patch*
You can start taking Yaz on the day after taking the last active tablet of the previous pills (the last tablet that includes active ingredients), but no later than the day after you finish taking the inactive tablets of the previous pills (or after taking the last inactive tablet of the previous pills).
When switching from a combined (vaginal) ring or patch, consult the doctor.
- *Switching from a progestogen-only contraceptive (pills, contraceptive injections or intrauterine device)*
You may switch from the progestogen-only pill to Yaz on any day you wish (start taking Yaz at the time of the next scheduled injection or on the day the intrauterine device is removed), but in all of these cases, you must use an additional contraceptive (e.g., a condom) during the first 7 days of taking Yaz.
- *After a miscarriage*
Consult the doctor.

- *After having a baby*

You can start taking Yaz between days 21 and 28 after having a baby. If you start later than day 28, use a barrier contraceptive (e.g., a condom) during the first 7 days of using Yaz.

If, after having a baby, you have had sex before you started taking Yaz, you must be sure that you are not pregnant or wait until your next period.

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

Read “Pregnancy and breastfeeding” in section 2.

First consult with the doctor.

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

Tests and follow-up

Before commencing use of Yaz, your doctor will ask you questions regarding your and your close family’s medical history. The doctor will measure your blood pressure and may perform other tests, in accordance with your medical condition.

If you need to have blood tests done, tell the doctor or laboratory staff that you are taking a combination pill, as hormonal contraceptives can affect the results of certain tests.

If you accidentally take too high a dosage

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

If you accidentally took several Yaz tablets at once, you may suffer from nausea or vomiting. Young girls may have vaginal bleeding.

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

If you forget to take the medicine

The last 4 tablets in the 4th row of the strip are inactive tablets. If you forget one of these tablets, this has no effect on the reliability of Yaz. Throw away the forgotten tablet.

If you forget a pink, active tablet (tablets 1-24 of the strip), you must act according to the following instructions:

- If the delay in taking a tablet is less than 24 hours, the protection against pregnancy is not reduced. Take the tablet as soon as you can and then continue taking the rest of the tablets as usual.
- If the delay in taking a tablet is more than 24 hours, the protection against pregnancy may be reduced. The greater the number of tablets you have forgotten, the greater is the risk of becoming pregnant.

The risk of incomplete protection against pregnancy is greater if you forget a pink tablet at the beginning or at the end of the strip. Therefore, keep to the following rules (see the “I forgot to take” diagram below and on the back of the package):

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

Consult the doctor.

- **You forgot to take one tablet between days 1-7 (1st row)**

Take the forgotten tablet as soon as possible, even if it means that you have to take 2 tablets at the same time. Continue taking the rest of the tablets as usual and use **additional contraceptives** (e.g., a condom) for the next 7 days. If you have had sex in the week before the day you forgot the tablet, you may be pregnant. In that case, consult the doctor.

- **You forgot to take one tablet between days 8-14 (2nd row)**

Take the forgotten tablet as soon as possible, even if it means that you have to take 2 tablets at the same time. Continue taking the rest of the tablets as usual. The protection against pregnancy is not reduced, and there is no need for use of additional contraceptives.

- **You forgot to take one tablet between days 15-24 (3rd or 4th row)**

You can choose between 2 possibilities:

1. Take the forgotten tablet as soon as possible, even if it means that you have to take 2 tablets at the same time. Continue taking the rest of the tablets as usual. Instead of taking the 4 white inactive tablets in the strip, discard them and start the next strip (the start day will change). You will most likely have a period at the end of the 2nd strip – when taking the white inactive tablets – but you may have bleeding or spotting while using the 2nd strip.
2. You can also stop taking the pink active tablets and immediately start taking the 4 white inactive tablets (**before taking the inactive tablets, record the day you forgot to take the tablet**). If you want to start a new strip on the day you normally start, take the inactive tablets for less than 4 days.

If you follow one of these 2 recommendations, you will remain protected against pregnancy.

- If you have forgotten any of the tablets in a strip, and you do not have bleeding during the days on which you are taking the inactive tablets, you may be pregnant. Refer to the doctor before you start the next strip.

Adhere to the treatment regimen recommended by the doctor.

"I forgot to take" Flowchart

You forgot to take more than one pink tablet in a strip

Consult with the attending doctor

Yes

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

No

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

You forgot to take only one pink tablet (a delay of more than 24 hours in taking)

Days 1-7

Days 8-14

Days 15-24

- Take the forgotten tablet
- Finish the strip of pills

- Take the forgotten tablet
- Finish taking the pink tablets in the strip
- Discard the 4 white tablets
- Start a new strip of pills

or

- Immediately stop taking the pink tablets
- Go on to taking the 4 white tablets
- Afterwards, start a new strip of pills

What to do in the case of vomiting or severe diarrhea

If you vomit within 3-4 hours of taking a pink active tablet or if you have severe diarrhea, there is a risk that the active ingredients in the tablet will not be fully taken up by your body. The situation is similar to a case in which you forget a tablet. After vomiting or diarrhea, take another pink tablet from another strip as soon as possible. If possible, take it within 24 hours of when you normally take the tablet. If that is not possible or more than 24 hours have passed, follow the instructions given under "If you forget to take the medicine"

Delaying your period: what you should do

Although it is not recommended, you can delay your period by skipping the white tablets in the 4th row, and immediately starting a new strip of Yaz until finishing it. You may experience spotting or menstruation-like bleeding while taking the 2nd strip. Finish taking the 2nd strip by taking the 4 white tablets in the 4th row. After that, start the next strip.

Consult the doctor before deciding to delay your period.

Changing the first day of your period: what you should do

If you take the tablets according to the instructions, your period will begin while taking the white tablets. If you have to change this day, shorten the period during which you take the placebo tablets – the days you take the white tablets – (but never make this period longer – 4 days is the maximum!). For example, if you start taking the white tablets on a Friday, and you want to change this to a Tuesday (3 days earlier), start a new strip 3 days earlier than usual. You may not have any bleeding during this time.

You may experience light or menstruation-like bleeding.

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

If you stop taking the medicine

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

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

If you have further questions regarding use of the medicine, consult the doctor or pharmacist.

4) SIDE EFFECTS

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

If you have one or more of the side effects, especially if it is severe or prolonged, or if there is a change in your health that you think can be related to Yaz, tell your doctor.

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

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

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

- mood swings
- headache
- nausea
- breast pain, menstrual disorders, such as irregular periods, absence of period

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

- depression, nervousness, sleepiness
- dizziness, 'pins and needles'
- migraine, varicose veins, increased blood pressure
- stomach ache, vomiting, indigestion, intestinal gas, inflammation of the stomach, diarrhea
- acne, itching, rash
- aches and pains, e.g., back pain, limb pain, muscle cramps
- vaginal fungal infection, pelvic pain, breast enlargement, occurrence of benign breast lumps, uterine/vaginal bleeding (which usually subsides with continued treatment), vaginal discharge, hot flushes, inflammation of the vagina (vaginitis), problems with your menstrual periods, painful periods, light periods, heavy periods, vaginal dryness, abnormal cervical smear tests result, decreased interest in sex
- lack of energy, increased sweating, fluid retention
- weight increase

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

- *Candida* (fungal infection)
- anemia, increase in the number of platelets in the blood
- allergic reaction
- hormonal (endocrine) disorders
- increased appetite, loss of appetite, abnormally high concentration of potassium in the blood, abnormally low concentration of sodium in the blood
- failure to experience an orgasm, insomnia
- giddiness, tremor
- eye disorders, e.g., inflammation of the eyelid, dry eyes
- abnormally rapid heartbeat
- inflammation of a vein, nosebleed, fainting
- enlarged abdomen, disturbed bowel activity, feeling bloated, stomach hernia, fungal infection of the mouth, constipation, dry mouth
- pain of bile ducts or the gallbladder, inflammation of the gallbladder
- yellow patches on the skin, eczema, hair loss, acne-like inflammation of the skin, dry skin, lumpy inflammation of the skin, excessive hair growth, skin disorders, stretch marks on the skin, skin inflammations, light-sensitive skin inflammations, skin nodules
- difficult or painful sex, inflammation of the genitals (vulvovaginitis), bleeding following intercourse, vaginal bleeding, occurrence of breast cysts, changes in breast tissue,

occurrence of malignant lumps in the breast, abnormal growth of the mucosal surface of the cervix, shrinkage or wasting of the lining of the womb, ovarian cysts, enlargement of the womb

- feeling generally unwell
- weight loss
- harmful blood clots in a vein or artery, for example:
 - in a leg or foot (deep vein thrombosis)
 - in a lung (pulmonary embolism)
 - heart attack
 - stroke
 - mini-stroke or temporary stroke-like symptoms, known as a transient ischemic attack (TIA)
 - blood clots in the liver, stomach or intestine, kidneys or eyes

The risk of having a blood clot may be higher if you have any other condition that increases this risk (for more information on risk factors and symptoms of a blood clot, see section 2 “Before Using the Medicine”).

The following side effects have also been reported, but the frequency of their occurrence is unknown from the available data:

Hypersensitivity, erythema multiforme (a rash including red “target-like” lesions or sores).

If you suffer from one of the side effects, if one of the side effects occurs or worsens, or if you suffer from a side effect not mentioned in the leaflet, consult with the doctor.

Side effects can be reported to the Ministry of Health by clicking on the “Reporting side effects following drug treatment” link found on the Ministry of Health homepage (www.health.gov.il) that directs you to the online form for reporting side effects, or by entering the link:

<https://forms.gov.il/globaldata/getsequence/getsequence.aspx?formType=AdversEffectMedic@moh.gov.il>

5) HOW SHOULD THE MEDICINE BE STORED?

- Avoid poisoning! This medicine and any other medicine must be kept in a safe place out of the reach of children and/or infants to avoid poisoning. Do not induce vomiting unless explicitly instructed to do so by the doctor.
- Do not use the medicine after the expiry date (exp. date) that appears on the package. The expiry date refers to the last day of that month.
- There are no special storage conditions. It is recommended to store at room temperature.
- Do not store different medicines in the same package.
- Do not discard the tablets in the waste bin. Consult a pharmacist regarding how to discard of medicines you no longer need. These measures will help protect the environment.

6) FURTHER INFORMATION

- In addition to the active ingredients, the medicine also contains:
Lactose monohydrate, maize starch, magnesium stearate, Lacquer pink or alternatively hypromellose 5cP, talc, titanium dioxide [E171], ferric oxide [E172], cellulose microcrystalline.

Each pink tablet contains: about 48 mg lactose.

Each white tablet contains: about 23 mg lactose.

- What the medicine looks like and the contents of the package

What the tablets look like:

- The active tablets are pink, round and with a rounded surface; one side has “DS” imprinted on it in a hexagon.
- The inactive tablets are white, round, and with a rounded surface; one side has “DP” imprinted on it in a hexagon.

Package contents:

- Each strip of Yaz contains 24 active, pink, film-coated tablets in the 1st, 2nd, 3rd and 4th rows, as well as 4 inactive, white, film-coated tablets in the 4th row.
- The tablets are provided in blister (tray) strips of 28 tablets. Each package contains 1, 3 or 6 strips.
- Not all package sizes may be marketed.
- Registration holder and address: Bayer Israel Ltd., 36 Hacharash St., Hod Hasharon 45240.
- Manufacturer name and address: Bayer Weimar GmbH und Co. KG, Weimar, Germany.
- This leaflet was checked and approved by the Ministry of Health in December 2015.
- Registration number of the medicine in the National Drug Registry of the Ministry of Health: 141 04 32023 00

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