

Package leaflet: Information for the user
YAZ PLUS

(drospirenone, ethinyl estradiol, levomefolate calcium tablets and levomefolate calcium tablets)

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

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

In this leaflet:

1. What YAZ PLUS is and what it is used for
2. What you need to know before you take YAZ PLUS
3. How to take YAZ PLUS
4. Possible side effects
5. How to store YAZ PLUS
6. Contents of the pack and other information

1. What YAZ PLUS is and what it is used for

YAZ PLUS is a birth control pill (oral contraceptive) that contains two female sex hormones, the progestin drospirenone (3.0 mg) and a low dose of the estrogen ethinyl estradiol (0.020 mg). The two female sex hormones are synthetic and similar to those that occur naturally in your body.

YAZ PLUS also contains levomefolate calcium, which is a B vitamin. When taken as prescribed by your doctor, YAZ PLUS has been shown to be highly effective in preventing pregnancy. Pregnancy is always more risky than taking birth control pills, except in smokers older than age 35.

Birth control pills work in two ways:

1. They inhibit the monthly release of an egg by the ovaries.
2. They change the mucus produced by the cervix. This slows the movement of the sperm through the mucus and through the uterus (womb).

Drospirenone in YAZ PLUS helps with androgen- (male sex hormone) related skin problems. Androgen circulates naturally within the female body. Androgens can cause glands in the skin to over-produce oil. This results in acne. YAZ PLUS works by lowering androgen levels in the body and by blocking the effects of androgens at the gland. As a result, a reduction in the number of acne breakouts is associated with YAZ PLUS treatment.

Levomefolate calcium in YAZ PLUS provides folate supplementation in women who choose to use an oral contraceptive. It is recommended that women who could become pregnant supplement their diet with a minimum of 0.4 mg (400 µg) of folic acid daily to lower the risk of having a pregnancy with a rare type of birth defect (known as a neural tube defect).

YAZ PLUS is used:

- To prevent pregnancy
- To treat moderate acne vulgaris in women 14 years of age and older who are able to use birth control pills and have achieved menarche. Your first menstrual period is referred to as menarche.
- To improve folate levels in women who choose to use an oral contraceptive

Effectiveness of Birth Control Pills

Combination birth control pills are more than 99 percent effective in preventing pregnancy when:

- the pill is **TAKEN AS DIRECTED**, and
- the amount of estrogen is 20 micrograms or more.

A 99 percent effectiveness rate means that if 100 women used birth control pills for one year, one woman in the group would get pregnant.

The chance of becoming pregnant increases with incorrect use.

Other Ways to Prevent Pregnancy

Other methods of birth control are available to you. They are usually less effective than birth control pills. When used properly, however, other methods of birth control are effective enough for many women.

The following table gives reported pregnancy rates for various forms of birth control, including no birth control. The reported rates represent the number of women out of 100 who would become pregnant in one year.

Reported Pregnancies per 100 Women per Year:

Combination pill	less than 1 to 2
Intrauterine device (IUD)	less than 1 to 6
Condom with spermicidal foam or gel	1 to 6
Mini-pill	3 to 6
Condom	2 to 12
Diaphragm with spermicidal foam or gel	3 to 18
Spermicide	3 to 21
Sponge with spermicide	3 to 28
Cervical cap with spermicide	5 to 18
Periodic abstinence (rhythm), all types	2 to 20
No birth control	60 to 85

Pregnancy rates vary widely because people differ in how carefully and regularly they use each method. (This does not apply to IUDs since they are implanted in the uterus.). Regular users may achieve pregnancy rates in the lower ranges. Others may expect pregnancy rates more in the middle ranges. The effective use of birth control methods other than birth control pills and IUDs requires more effort than taking a single pill every day. It is an effort that many couples undertake successfully.

2. What you need to know before you take YAZ PLUS

Do not take YAZ PLUS

The birth control pill is not suitable for every woman. In a small number of women, serious side effects may occur. Your doctor can advise you if you have any conditions that would pose a risk to you. The use of the birth control pill always should be supervised by your doctor.

You should not use YAZ PLUS if you have or have had any of the following conditions:

- blood clots in the legs, lungs, eyes, or elsewhere, or thrombophlebitis (inflammation or swelling of the veins)
- stroke, heart attack, or coronary artery disease (eg, angina pectoris), or a condition that may be a first sign of a stroke (such as a transient ischemic attack or small reversible stroke)
- disease of the heart valves with complications
- known abnormalities of the blood clotting system that increases your risk for developing blood clots
- severe high blood pressure
- diabetes with complications
- very high blood cholesterol or triglyceride levels
- you smoke and are over age 35
- migraine headache
- you are scheduled for major surgery

- prolonged bed rest
- you are taking ombitasvir, paritaprevir, ritonavir, with or without dasabuvir for the treatment of Hepatitis C
- jaundice (yellowing of the eyes or skin), liver disease, or liver tumor
- known or suspected cancer of the breast or uterus (womb) or other estrogen-dependent cancer
- unusual vaginal bleeding without a known reason
- loss of vision due to blood vessel disease of the eye
- you are pregnant or suspect you may be pregnant
- pancreatitis (inflammation of the pancreas) associated with high levels of fatty substances in your blood
- allergy (hypersensitivity) to ethinyl estradiol, drospirenone, levomefolate calcium or to any of the other ingredients in YAZ PLUS (see "Contents of the pack and other information")

- In addition, you should not use YAZ PLUS if you have any of the following conditions:

- Kidney disease
- Liver disease
- Adrenal disease

Tell your doctor if you have ever had any of the above conditions (your doctor can recommend another method of birth control).

Warning and precautions

Serious Warnings and Precautions

Cigarette smoking increases the risk of serious adverse effects on the heart and blood vessels. This risk increases with age and becomes significant in hormonal contraceptive users older than 35 years of age, and with the number of cigarettes smoked. For this reason, combination oral contraceptives, including YAZ PLUS, should not be used by women who are over 35 years of age and smoke. Women should not smoke. Birth control pills DO NOT PROTECT against sexually transmitted infections (STIs), including HIV/AIDS. For protection against STIs, it is advisable to use latex or polyurethane condoms IN COMBINATION WITH birth control pills.

YAZ PLUS is a birth control pill containing estrogen and progestin and a vitamin (levomefolate calcium). The progestin in YAZ PLUS is known as drospirenone and it may increase the levels of potassium in your blood. Therefore, you should not take YAZ PLUS if you have kidney, liver, or adrenal disease (a disease that may alter the body's fluid and mineral balance) because this could cause serious heart and health problems. Other drugs may also increase potassium (see "Before you use YAZ PLUS, talk to your doctor or pharmacist if you"). During the first month that you take YAZ PLUS, you should have a blood test to check your potassium level.

Do not use YAZ PLUS if you are taking ombitasvir, paritaprevir, ritonavir, with or without dasabuvir for the treatment of Hepatitis C. Using these drugs at the same time as YAZ PLUS has the potential to cause liver problems, such as an increase in the ALT liver enzyme. You can usually start YAZ PLUS about 2 weeks after finishing treatment with this combination of drugs used for Hepatitis C, but always consult with your doctor or pharmacist.

It has been reported that drospirenone, the progestin in YAZ PLUS, may carry a higher risk of blood clots than some other progestins (including levonorgestrel). You should talk to your doctor about the available options.

BEFORE you use YAZ PLUS, talk to your doctor or pharmacist if you:

- smoke
- are overweight
- have a history of breast disease (eg, breast lumps) or a family history of breast cancer
- have high blood pressure
- have high cholesterol
- have diabetes

- have heart or kidney disease
- have a history of seizures/epilepsy
- have a history of depression
- have a history of liver disease or jaundice
- wear contact lenses
- have uterine fibroids (benign tumors of the uterus)
- may be pregnant or are breastfeeding
- have systemic lupus erythematosus
- have inflammatory bowel disease such as Crohn's disease or ulcerative colitis
- have haemolytic uremic syndrome
- have sickle cell disease
- have any problems with the valves in your heart and/or have an irregular heart rhythm
- if you suffer from vitamin B12 deficiency (for example due to a reduced B12 diet such as a strict vegetarian diet, due to a history of gastrointestinal surgery or certain types of gastritis) tell your doctor that you use YAZ PLUS because folates may hide vitamin B12 deficiency
- have been told that you have a condition called hereditary angioedema or if you have had episodes of swelling in body parts such as hands, feet, face, or airway passages
- you are currently on daily, long-term treatment for a chronic condition with any of the medications listed below:
 - Non-steroidal anti-inflammatory drugs (NSAIDs) when taken long-term and for treatment of arthritis or other problems (eg, ibuprofen, naproxen, or others)
 - Potassium-sparing diuretics (spironolactone and others)
 - Potassium supplements
 - ACE inhibitors and Angiotensin-II receptor antagonists for the treatment of high blood pressure (eg, captopril, enalapril, lisinopril, losartan, valsartan, irbesartan, or others)
 - Heparin

You should also inform your doctor about a family history of blood clots, heart attacks, or strokes. Inform your doctor if you are taking daily folate supplements.

YAZ PLUS contains the equivalent of 0.4 mg of folic acid.

If you see a different doctor, inform him or her that you are using YAZ PLUS.

Tell your doctor if you are scheduled for any laboratory tests since certain blood tests may be affected by hormonal contraceptives.

Also tell your doctor if you are scheduled for MAJOR surgery.

You should consult your doctor about stopping the use of YAZ PLUS four weeks before surgery and not using YAZ PLUS for a time period after surgery or during bed rest.

YAZ PLUS should be used only under the supervision of a doctor, with regular follow-up to identify side effects associated with its use. Your visits may include a blood pressure check, a breast exam, an abdominal exam and a pelvic exam, including a Pap smear. Visit your doctor three months or sooner after the initial examination. Afterward, visit your doctor at least once a year. Use YAZ PLUS only on the advice of your doctor and carefully follow all directions given to you. You must use the birth control pill exactly as prescribed. Otherwise, you may become pregnant.

The risks of using YAZ PLUS

If you and your doctor decide that, for you, the benefits of YAZ PLUS outweigh the risks, you should be aware of the following:

1. Circulatory disorders (including blood clot in legs, lungs, heart, eyes, or brain)

Women who use hormonal contraceptives have a higher incidence of blood clots. Blood clots are the most common serious side effects of birth control pills. The risk of developing blood clots is especially high during

the first year a woman ever uses a hormonal contraceptive or restarts the same or a different hormonal contraceptive. Clots can occur in many parts of the body.

Be alert for the following symptoms and signs of serious adverse effects.

Call your doctor immediately if they occur:

- sharp pain in the chest which may increase with deep breathing; coughing blood; sudden shortness of breath or rapid breathing; sense of anxiety; severe light headedness or dizziness; rapid or irregular heartbeat. These symptoms could indicate a possible blood clot in the lung.
- pain and/or swelling in the calf or along a vein in the leg; pain or tenderness in the leg which may be felt only when standing or walking, increased warmth in the affected leg; red or discoloured skin on the leg. These symptoms could indicate a possible blood clot in the leg.
- crushing chest pain, discomfort, pressure, heaviness, sensation of squeezing or fullness in the chest, arm, or below the breastbone; discomfort radiating to the back, jaw, throat, arm, stomach; fullness, indigestion or choking feeling; sweating, nausea, vomiting or dizziness; extreme weakness, anxiety, or shortness of breath; rapid or irregular heartbeats. These symptoms could indicate a possible heart attack.
- sudden severe or worsening headache or vomiting; sudden trouble walking, dizziness, loss of balance or coordination; loss of consciousness or fainting with or without seizure; sudden confusion, disturbances of vision, speech or understanding; sudden weakness or numbness of the face, arm or leg. These symptoms could indicate a possible stroke.
- sudden partial or complete loss of vision. This symptom could indicate a blood clot in the eye.
- other signs of a blood clot can include sudden pain, swelling and slight blue discoloration of an extremity; acute abdomen.

Any of these conditions can cause death or disability. Clots also occur rarely in the blood vessels of the eye, resulting in blindness or impaired vision or in a blood vessel leading to an arm or leg, resulting in damage to or loss of a limb.

The risk of clotting seems to increase with higher estrogen doses. It is important, therefore, to use as low a dosage of estrogen as possible.

Cancer of the breast, cervix, or liver may be life-threatening or may result in death.

2. Breast cancer

The most significant risk factors for breast cancer are increasing age and a strong history of breast cancer in the family (mother or sister). Other established risk factors include obesity, never having children, and having your first full-term pregnancy at a late age.

Some women who use hormonal contraceptives may be at increased risk of developing breast cancer before menopause, which occurs around age 50. These women may be long-term users of birth control pills (more than eight years) or women who start using birth control pills at an early age. In a few women, the use of birth control pills may accelerate the growth of an existing but undiagnosed breast cancer. Early diagnosis, however, can reduce the effect of breast cancer on a woman's life expectancy.

The potential risks related to birth control pills seem to be small, however. A yearly breast examination by a health care professional is recommended for all women.

ASK YOUR DOCTOR FOR ADVICE AND INSTRUCTIONS ON REGULAR SELF-EXAMINATION OF YOUR BREASTS.

3. Cervical cancer

Some studies have found an increase of cancer of the cervix in women who use hormonal contraceptives, although this finding may be related to factors other than the use of oral contraceptives. However, there is insufficient evidence to rule out the possibility that oral contraceptives may cause such cancers.

4. Liver tumors

The short and long-term use of birth control pills have also been linked with the growth of liver tumors. Such tumors are **extremely** rare.

Contact your doctor immediately if you experience severe pain or a lump in the abdomen.

5. Gallbladder disease

Users of birth control pills have a greater risk of developing gallbladder disease requiring surgery within the first year of use. The risk may double after four or five years of use.

Other medicines and Yaz PLUS

Certain drugs may interact with birth-control pills to make them less effective in preventing pregnancy or cause an increase in breakthrough bleeding. Please inform your doctor or pharmacist if you are taking or have recently taken any other drugs or herbal products, even those without a prescription. Also tell any other doctor or dentist (or the dispensing pharmacist) who prescribes another drug that you use YAZ PLUS. They can tell you if you need to use an additional method of contraception and if so, for how long.

Drugs that may interact with YAZ PLUS include:

- drugs used for the treatment of epilepsy (eg, primidone, phenytoin, barbiturates, carbamazepine, oxcarbazepine, topiramate, felbamate, phenobarbital, valproic acid); tuberculosis (eg, rifampin, rifabutin), HIV infections (eg, ritonavir, nevirapine), and Hepatitis C Virus infections (eg, boceprevir, telaprevir)
- antibiotics (eg, penicillins, tetracyclines, clarithromycin, erythromycin) for infectious diseases
- cyclosporine
- ombitasvir, paritaprevir, ritonavir, with or without dasabuvir (used to treat Hepatitis C)
- antifungals (eg, griseofulvin, fluconazole, itraconazole, ketoconazole, voriconazole)
- cholesterol-lowering drugs (eg, clofibrate)
- drugs used for the treatment of certain heart diseases or high blood pressure (eg, diltiazem, verapamil)
- antidiabetic drugs and insulin (for diabetes)
- prednisone
- sedatives and hypnotics (eg, benzodiazepines, barbiturates, chloral hydrate, glutethimide, meprobamate)
- pain medication (meperidine)
- antidepressants (eg, clomipramine)
- tizanidine (drug used for multiple sclerosis [MS])
- theophylline (drug used for asthma)
- some nutritional supplements (eg, Vit. B12, folic acid)
- antacids (use 2 hours before or after taking YAZ PLUS)
- drugs that may decrease folate levels (eg, methotrexate, trimethoprim, sulfasalazine, triamteren, cholestyramine, and antiepileptic drugs listed above)

YAZ PLUS may also interfere with the working of other drugs.

Herbal or food products that may interact with YAZ PLUS include:

- the herbal remedy St. John's wort (primarily used for the treatment of depressive moods)
- grapefruit juice

This is not a complete list of possible drug interactions with YAZ PLUS. Talk to your doctor for more information about drug interactions.

Pregnancy and Breast-feeding

Use in pregnancy

Birth control pills should not be taken by pregnant women. There is no evidence, however, that the birth control pill can damage a developing child. You should check with your doctor about risks to your unborn child from any medication taken during pregnancy. Also, check with your doctor about appropriate folate supplementation if you stop taking YAZ PLUS, are pregnant, or plan on becoming pregnant.

Use after pregnancy, miscarriage or an abortion

Your doctor will advise you of the appropriate time to start the use of YAZ PLUS after childbirth, miscarriage, or therapeutic abortion.

Pregnancy after stopping YAZ PLUS

You will have a menstrual period when you stop using YAZ PLUS. You should delay pregnancy until another menstrual period occurs within four to six weeks. In this way the pregnancy can be more accurately dated. Contact your doctor for recommendations on alternate methods of contraception during this time.

Breast-feeding

If you are breastfeeding, consult your doctor before starting the birth control pill. The hormones in birth control pills are known to appear in breast milk. These hormones may decrease the flow of breast milk. If birth control pills are not resumed until nursing is established, however, the quantity and quality of breast milk does not seem to be affected. Adverse effects on the child have been reported, including yellowing of the skin (jaundice) and breast enlargement. You should use another method of contraception and only consider starting the birth control pill once you have weaned your child completely.

Driving and Using machines

No studies on the effects of YAZ PLUS on the ability to drive or use machines have been performed.

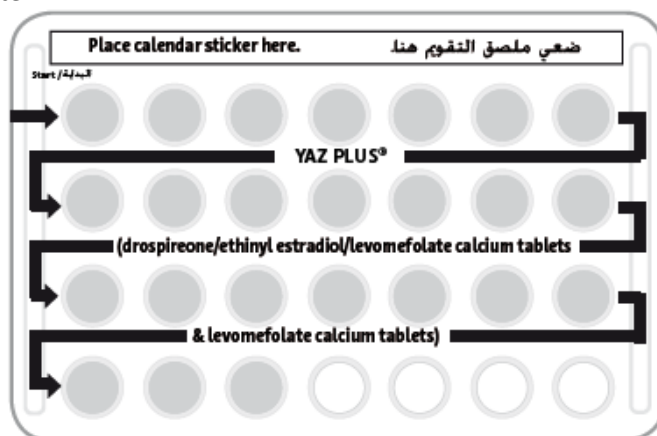
3. How to take YAZ PLUS

Always take YAZ Plus exactly as your doctor or health care provider has told you. You should check with your doctor or pharmacist if you are not sure.

1. Read these directions before you start taking your pills, and at any time you are not sure what to do.

2. LOOK AT YOUR PILL PACK, it has 28 pills.

The YAZ PLUS pill pack has 24 hormone-containing pink “active” pills to be taken for 24 days, followed by 4 hormone-free light-orange pills to be taken for four days. It is important to take the light-orange pills because they contain folate.



ALSO CHECK the pill pack for: 1) where to start, and 2) direction to take pills in (follow the arrows).

- 3.** You should use a second method of birth control (eg, latex or polyurethane condoms and spermicidal foam or gel) for the first seven days of the first cycle of pill use. This will provide a backup in case pills are forgotten while you are getting used to taking them.
- 4. When receiving any medical treatment, be sure to tell your doctor that you are using birth control pills.**
- 5. IF YOU EXPERIENCE VOMITING OR DIARRHEA, OR IF YOU TAKE CERTAIN MEDICINES,** such as antibiotics, your pills may not work as well. Use a back-up method, such as latex or polyurethane condoms and spermicidal foam or gel, until you can check with your doctor or clinic.
- 6.** Visit your doctor three months or sooner after the initial examination. Afterward, visit your doctor at least once a year.

7. Take the pills only on the advice of your doctor and carefully follow all directions given to you. You must take the pills exactly as prescribed. Otherwise, you may become pregnant.
8. Your doctor will advise you of the appropriate time to start the use of birth control pills after childbirth, miscarriage, or therapeutic abortion.
9. **THERE IS NO NEED TO STOP TAKING BIRTH CONTROL PILLS FOR A REST PERIOD.**
10. **IF YOUR QUESTIONS ARE NOT ANSWERED HERE, CALL YOUR DOCTOR OR CLINIC.**

WHEN TO START THE *FIRST* PACK OF PILLS

BE SURE TO READ THESE INSTRUCTIONS before you start taking your pills, and at any time you are not sure what to do.

Decide with your doctor or clinic what is the best day for you to start taking your first pack of pills. Pick a time of day which will be easy to remember.

1. **THE FIRST DAY OF YOUR MENSTRUAL PERIOD (BLEEDING) IS DAY 1 OF YOUR CYCLE.** Your doctor may advise you to start taking the pills on Day 1 or on the first Sunday after your period begins. If your period starts on Sunday, start that same day.
2. Take one pill at approximately the same time every day for 28 days. Begin a new pack the next day, **NOT MISSING ANY DAYS.** Your period should occur during the last four days of using that pill pack.

WHAT TO DO DURING THE MONTH

1. **TAKE A PILL AT APPROXIMATELY THE SAME TIME EVERY DAY UNTIL THE PACK IS EMPTY.**

- Try to associate taking your pill with some regular activity, such as eating a meal or going to bed.
- Do not skip pills even if you have bleeding between monthly periods or feel sick to your stomach (nausea).
- Do not skip pills even if you do not have sex very often.

2. **WHEN YOU FINISH A PACK**

Start the next pack on the day after your last hormone-free light-orange pill. Take one pill every day. **It is important to take the light-orange pills because they contain folate.** Do not wait any days between packs.

If you take more YAZ Plus than you should

Symptoms of overdose may include nausea, vomiting, or vaginal bleeding. Even girls who have not yet had their first menstrual period but have accidentally taken this medicine may experience such bleeding.

Available information from cases of accidental ingestion of oral contraceptives by children indicates no serious effects.

In case of drug overdose, contact a health care practitioner, hospital emergency department, or regional Poison Control Center immediately, even if there are no symptoms.

If you forget to take YAZ Plus

MISSING PILLS CAN CAUSE SOME SPOTTING OR LIGHT BLEEDING, even if you make up the missed pills.

You also could feel a little sick to your stomach on the days you take two pills to make up for missed pills.

IF YOU MISS PILLS AT ANY TIME, YOU COULD GET PREGNANT. THE GREATEST RISKS FOR PREGNANCY ARE:

- when you start a pack late, or
- when you miss pills at the beginning or at the very end of the pack.

WHAT TO DO IF YOU MISS PILLS

The following table outlines the actions you should take if you miss one or more of your birth control pills. Match the number of pills missed with the appropriate starting time for your type of pill pack.

Sunday Start	Other than Sunday Start
Miss One Pink Pill at Any Time	Miss One Pink Pill at Any Time
Take it as soon as you remember, and take the next pill at the usual time. This means that you	Take it as soon as you remember, and take the next pill at the usual time. This means that you

might take two pills in one day.	might take two pills in one day.
Miss Two Pink Pills in a Row	Miss Two Pink Pills in a Row
First Two Weeks: 1. Take two pills the day you remember and two pills the next day. 2. Then take one pill a day until you finish the pack. 3. Use a back-up (barrier) method of birth control if you have sex in the seven days after you miss the pills.	First Two Weeks: 1. Take two pills the day you remember and two pills the next day. 2. Then take one pill a day until you finish the pack. 3. Use a back-up (barrier) method of birth control if you have sex in the seven days after you miss the pills.
Third and Fourth Weeks 1. Keep taking one pill a day until Sunday. 2. On Sunday, safely discard the rest of the pack and start a new pack that day. 3. Use a back-up (barrier) method of birth control if you have sex in the seven days after you miss the pills. 4. You may not have a period this month. If you miss two periods in a row, call your doctor or clinic.	Third and Fourth Weeks 1. Safely dispose of the rest of the pill pack and start a new pack that same day. 2. Use a back-up (barrier) method of birth control if you have sex in the seven days after you miss the pills. 3. You may not have a period this month. If you miss two periods in a row, call your doctor or clinic.
Miss Three or More Pink Pills in a Row	Miss Three or More Pink Pills in a Row
Anytime in the Cycle 1. Keep taking one pill a day until Sunday. 2. On Sunday, safely discard the rest of the pack and start a new pack that day. 3. Use a back-up (barrier) method of birth control if you have sex in the seven days after you miss the pills. 4. You may not have a period this month. If you miss two periods in a row, call your doctor or clinic.	Anytime in the cycle 1. Safely dispose of the rest of the pill pack and start a new pack that same day. 2. Use a back-up (barrier) method of birth control if you have sex in the seven days after you miss the pills. 3. You may not have a period this month. If you miss two periods in a row, call your doctor or clinic.

NOTE: If you forget any of the four hormone-free light-orange pills (containing folate) in Week 4, just safely dispose of the pills you missed. Then keep taking one pill each day until the pack is empty. You do not need to use a back-up method.

Always be sure you have on hand

- a backup method of birth control (such as latex or polyurethane condoms and spermicidal foam or gel) in case you miss pills, and
- an extra, full pack of pills.

IF YOU FORGET MORE THAN ONE PILL TWO MONTHS IN A ROW, TALK TO YOUR DOCTOR OR CLINIC about ways to make pill-taking easier or about using another method of birth control.

If you have any further questions on the use of this product, ask your doctor or pharmacist.

4. Possible Side Effects

Like all medicines, YAZ Plus can cause side effects, although not everybody gets them.

The following side effects have been observed in studies of women taking YAZ PLUS which may or may not be drug related:

Most side effects when using the birth control pill are not serious. The most common side effects are nausea, vomiting, bleeding or spotting between menstrual periods, breast pain, acne, itching, migraine, dizziness, emotional lability (sudden changes in emotional state without a reason), dysmenorrhea (painful menstrual cramps), headache, vaginal yeast infection, depression, back pain, abdominal pain, nervousness, rash.

Other side effects can occur such as gastrointestinal symptoms (abdominal cramps and bloating), darkening of the skin (particularly on the face), change in appetite, change in libido (sex drive), hair loss, change in weight (increase or decrease), swelling, breast changes (tenderness, enlargement, discharge), temporary infertility after discontinuation of treatment.

If you experience new onset of high blood pressure or worsening of high blood pressure, contact your doctor or pharmacist.

The following additional symptoms have been reported in women taking hormonal contraceptives in general:

- difficulty wearing contact lenses
- vaginal irritation or infections
- urinary tract infections or inflammation
- upper respiratory tract infections (colds, bronchitis, runny or stuffy nose, sore throat, etc)
- severe headaches
- depression, insomnia, nervousness
- amenorrhea (lack of a period or breakthrough bleeding)
- back pain
- abdominal pain
- flu-like symptoms
- allergy, fatigue, fever
- diarrhea, flatulence
- rash

Many women have spotting or light bleeding, or may feel sick to their stomach during the first three months on the pill. If you do feel sick, do not stop taking the pill. The problem will usually go away. If it does not go away, check with your doctor or clinic.

Serious Uncommon Side Effects:

Talk with your doctor or pharmacist in all cases if any of below happens:

- Abdominal pain, nausea or vomiting or lump in the abdomen
- Breast lump
- Unexpected vaginal bleeding
- Unusual swelling of the extremities

Stop taking drug and call your doctor or pharmacist if any of below happens:

- Crushing chest pain or heaviness
- Pain or swelling in the leg
- Persistent sad mood
- Sharp pain in the chest, coughing blood, or sudden shortness of breath
- Sudden partial or complete loss of vision or double vision
- Sudden severe headache or worsening of headache, vomiting, dizziness, fainting, disturbance of vision or speech, or weakness or numbness in the face, arm or leg
- Yellowing of the skin or eyes (jaundice)

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor, health care provider or pharmacist.

To report any side effect(s):

National Pharmacovigilance and Drug Safety Center (NPC).

Fax: + 966 - 11 - 205 - 7662.

Call NPC at +966 - 11 - 2038222,

Ext.: 2317 - 2356 - 2340.

Reporting hotline: 19999

E - mail: npc.drug@sfd.gov.sa.

Website: www.sfd.gov.sa/npc

5. How to store YAZ PLUS

- *Keep out of the reach and sight of children.*
- *Store below 30°C in the original packaging.*
- *Protect from heat and moisture*
- *Do not use YAZ Plus after the expiry date which is stated on the package, 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 of medicines no longer required. These measures will help to protect the environment.*

6. Contents of the pack and other information***What YAZ Plus contains:***

The active ingredients are:

Each hormone-containing pink, film-coated tablet contains:

Drospirenone 3.0 mg

Ethinyl estradiol 0.020 mg

Levomefolate calcium 0.451 mg

The light-orange tablets are hormone-free and contain 0.451 mg levomefolate calcium.

The other ingredients are:

Cellulose microcrystalline, croscarmellose sodium, ferric oxide red, ferric oxide yellow, hydroxypropylcellulose 5 cp, hypromellose 5 cp, lactose monohydrate, macrogol 6000, magnesium stearate, talc, titanium dioxide, β-cyclodextrin

What YAZ Plus looks like and content of the pack:

YAZ Plus tablets are available in a 28- day regimen.

Each blister pack contains 24 hormone-containing pink and 4 hormone-free light-orange, film-coated, round tablets.

Manufacturer

Bayer Weimar GmbH & Co. KG

D-99427 Weimar, Germany.

Marketing Authorisation Holder

Bayer Pharma AG

D-13342 Berlin, Germany.

This leaflet was last approved in 2 March 2017.

This is a medicament

- A medicament is a product which affects your health and its consumption contrary to instructions is dangerous for you.
- Follow strictly the doctor's prescription, the method of use and the instructions of the pharmacist who sold the medicament.
- The doctor and the pharmacist are experts in medicine, its benefits and risks.
- Do not by yourself interrupt the period of treatment prescribed.
- Do not repeat the same prescription without consulting your doctor.

Keep medicament out of reach of children

Council of Arab Health Ministers

Union of Arab Pharmacists