

inert white round, unscored, film-coated tablets debossed with a "DP" in a regular hexagon on one side.

Store at 25° C (77° F); excursions permitted to 15-30°C (59-86°F) [See USP Controlled Room Temperature].

REFERENCES FURNISHED UPON REQUEST

Manufactured for: Berlex Laboratories
Manufactured in: Germany

BRIEF SUMMARY PATIENT PACKAGE INSERT

YAZ

(drospirenone and ethinyl estradiol) Tablets

containing the following:

24 light pink - "active" tablets

4 white – "inert" tablets

This product (like all oral contraceptives) is intended to prevent pregnancy. It does not protect against HIV infection (AIDS) and other sexually transmitted diseases.

YAZ is different from other birth-control pills because it contains the progestin drospirenone. Drospirenone may increase potassium. Therefore, you should not take YAZ if you have kidney, liver or adrenal disease because this could cause serious heart and health problems. Other drugs may also increase potassium. If you are currently on daily, long-term treatment for a chronic condition with any of the medications below, you should consult your healthcare provider about whether YAZ is right for you, and during the first month that you take YAZ, you should have a blood test to check your potassium level.

- **NSAIDs (ibuprofen [Motrin, Advil], naprosyn [Aleve and others] when taken long-term and daily for treatment of arthritis or other problems)**
- **Potassium-sparing diuretics (spironolactone and others)**
- **Potassium supplementation**
- **ACE inhibitors (Capoten, Vasotec, Zestril and others)**
- **Angiotensin-II receptor antagonists (Cozaar, Diovan, Avapro and others)**
- **Heparin**
- **Aldosterone antagonists**

YAZ is an oral contraceptive, also known as a "birth control pill" or "the Pill." Oral contraceptives are taken to prevent pregnancy, and, when taken correctly without missing any pills, have a failure rate of approximately 1% per year (1 pregnancy per 100 women per year of use). The typical failure rate in pill users is approximately 5% per year (5 pregnancies per 100 women per year of use) when women who miss pills are included. Forgetting to take pills considerably increases the chances of pregnancy.

YAZ may also be taken to treat premenstrual dysphoric disorder (PMDD) if you choose to use the Pill for birth control. Unless you have already decided to use the Pill for birth control, you should not start YAZ to treat your PMDD because there are other medical therapies for PMDD that do not have the same risks as the Pill. PMDD is a mood disorder related to the menstrual cycle. PMDD significantly

interferes with work or school, or with usual social activities and relationships with others. Symptoms include markedly depressed mood, anxiety or tension, mood swings, and persistent anger or irritability. Other features include decreased interest in usual activities, difficulty concentrating, lack of energy, change in appetite or sleep, and feeling out of control. Physical symptoms associated with PMDD may include breast tenderness, headache, joint and muscle pain, bloating and weight gain. These symptoms occur regularly before menstruation starts and go away within a few days following the start of the period. Diagnosis of PMDD should be made by healthcare providers.

You should only use YAZ for treatment of PMDD if you:

- Have already decided to use oral contraceptives for birth control, and
- Have been diagnosed with PMDD by your healthcare provider.

YAZ has not been shown to be effective for the treatment of premenstrual syndrome (PMS), a less serious cluster of symptoms occurring before menstruation. If you or your healthcare provider believes you have PMS, you should only take YAZ if you want to prevent pregnancy; and not for the treatment of PMS.

YAZ may also be taken to treat moderate acne in women who are able to and wish to use the pill for birth control.

Any woman who needs contraception (birth control) and chooses to use an oral contraceptive should understand the benefits and risks of using the Pill. This leaflet will give you much of the information you will need to help you decide if you should use the Pill for contraception and will also help you determine if you are at risk of developing any of the serious side effects of the Pill. It will tell you how to use the Pill properly so that it will be as effective as possible. However, this leaflet is not a replacement for a careful discussion between you and your healthcare professional. You should discuss the information provided in this leaflet with him or her, both when you first start taking the Pill and during your revisits. You should also follow your healthcare professional's advice with regard to regular check-up while you are on the Pill.

For the majority of women, oral contraceptives can be taken safely. But there are some women who are at high risk of developing certain serious diseases that can be life-threatening or may cause temporary or permanent disability or death. The risks associated with taking oral contraceptives increase significantly if you:

- smoke
- have high blood pressure, diabetes, high cholesterol, or are obese
- have or have had clotting disorders, heart attack, stroke, angina pectoris (severe chest pains), cancer of the breast or sex organs, jaundice, or malignant or benign liver tumors.

You should not take the pill if you suspect you are pregnant or have unexplained vaginal bleeding.

Although cardiovascular disease risks may be increased with oral contraceptive use after age 40 in healthy, non-smoking women (even with the newer low-dose formulations), there are also greater potential health risks associated with pregnancy in older women.

Cigarette smoking increases the risk of serious adverse effects on the heart and blood vessels from oral contraceptive use. This risk increases with age and with heavy smoking (15 or more cigarettes per day) and is quite marked in women over 35 years of age. Women who use oral contraceptives should not smoke.

Most side effects of the pill are not serious. The most common such effects are nausea, vomiting, bleeding between menstrual periods, weight gain, breast tenderness, and difficulty wearing contact lenses. These side effects, especially nausea and vomiting may subside within the first three months of use.

The serious side effects of the pill occur very infrequently, especially if you are in good health and are young. However, you should know that the following medical conditions have been associated with or made worse by the pill:

1. Blood clots in the legs (thrombophlebitis), lungs (pulmonary embolism), blockage or rupture of a blood vessel in the brain (stroke), blockage of blood vessels in the heart (heart attack and angina pectoris) or other organs of the body. As mentioned above, smoking increases the risk of heart attacks and strokes and subsequent serious medical consequences. Women with migraine headaches also may be at increased risk of stroke when taking the pill.
2. Liver tumors, which may rupture and cause severe bleeding. A possible but not definite association has been found with the pill and liver cancer. However, liver cancers are extremely rare. The chance of developing liver cancer from using the pill is thus even rarer.
3. High blood pressure, although blood pressure usually returns to normal when the pill is stopped.
4. Cancer of the breast. Various studies give conflicting reports on the relationship between breast cancer and oral contraceptive use. Oral contraceptive use may slightly increase your chance of having breast cancer diagnosed, particularly after using hormonal contraceptives at a younger age. After you stop using hormonal contraceptives, the chances of getting breast cancer begin to go back down. You should have regular breast examinations by a healthcare provider and examine your own breasts monthly. Tell your healthcare provider if you have a family history of breast cancer or if you have had breast nodules or an abnormal mammogram. Women who currently have or have had breast cancer should not use oral contraceptives because breast cancer is a hormone-sensitive tumor.

Some studies have found an increase in the incidence of cancer or precancerous lesions of the cervix in women who use the pill. However, this finding may be related to factors other than the use of the pill.

The symptoms associated with these serious side effects are discussed in the detailed leaflet given to you with your supply of pills. Notify your doctor or healthcare provider if you notice any unusual physical disturbances while taking the pill. In addition, drugs such as rifampin, as well as some anticonvulsants, some antibiotics and some herbal products such as St. John's Wort, may decrease oral contraceptive effectiveness.

Taking the pill may provide some important non-contraceptive benefits. These include less painful menstruation, less menstrual blood loss and anemia, fewer pelvic infections, and fewer cancers of the ovary and the lining of the uterus.

Be sure to discuss any medical condition you may have with your healthcare provider. Your healthcare provider will take a medical and family history before prescribing oral contraceptives and

will examine you. The physical examination may be delayed to another time if you request it and the healthcare provider believes that it is appropriate to postpone it. You should be reexamined at least once a year while taking oral contraceptives. The detailed patient information booklet gives you further information which you should read and discuss with your healthcare provider.

This product (like all oral contraceptives) is intended to prevent pregnancy. Oral contraceptives do not protect against HIV infection (AIDS) and other sexually transmitted diseases such as chlamydia, genital herpes, genital warts, gonorrhea, hepatitis B, and syphilis.

INSTRUCTIONS TO PATIENTS

HOW TO TAKE THE PILL

IMPORTANT POINTS TO REMEMBER

BEFORE YOU START TAKING YOUR PILLS:

1. BE SURE TO READ THESE DIRECTIONS:

Before you start taking your pills.

Anytime you are not sure what to do.

2. THE RIGHT WAY TO TAKE THE PILL IS TO TAKE ONE PILL EVERY DAY AT THE SAME TIME. YAZ CAN BE TAKEN WITHOUT REGARD TO MEALS.

If you miss pills you could get pregnant. This includes starting the pack late. The more pills you miss, the more likely you are to get pregnant. See “**WHAT TO DO IF YOU MISS PILLS**” below.

3. MANY WOMEN HAVE SPOTTING OR LIGHT BLEEDING, OR MAY FEEL SICK TO THEIR STOMACH DURING THE FIRST 1-3 PACKS OF PILLS.

If you do have spotting or light bleeding or feel sick to your stomach, do not stop taking the pill. The problem will usually go away. If it does not go away, check with your healthcare provider.

4. MISSING PILLS CAN ALSO CAUSE SPOTTING OR LIGHT BLEEDING, even when you make up these missed pills.

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

5. IF YOU HAVE VOMITING (within 3 to 4 hours after you take your pill), you should follow the instructions for “**WHAT TO DO IF YOU MISS PILLS**”. IF YOU HAVE DIARRHEA, or IF YOU TAKE CERTAIN MEDICINES, including some antibiotics and some herbal products such as St. John’s Wort, your pills may not work as well.

Use a back-up method (such as condoms or spermicides) until you check with your healthcare provider.

6. IF YOU HAVE TROUBLE REMEMBERING TO TAKE THE PILL, talk to your healthcare provider about how to make pill-taking easier or about using another method of birth control.

7. IF YOU HAVE ANY QUESTIONS OR ARE UNSURE ABOUT THE INFORMATION IN THIS LEAFLET, call your healthcare provider.

BEFORE YOU START TAKING YOUR PILLS

1. DECIDE WHAT TIME OF DAY YOU WANT TO TAKE YOUR PILL.

It is important to take YAZ at about the same time every day. YAZ can be taken without regard to meals.

2. LOOK AT YOUR PILL PACK: – IT HAS 28 PILLS:

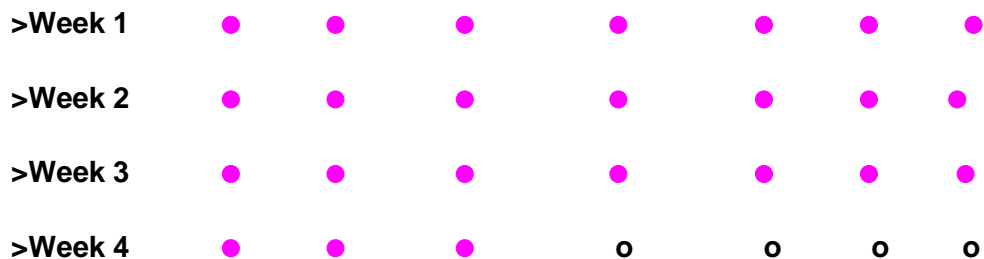
The YAZ-*pill pack* has 24 light pink "active" pills (with hormones) to be taken for 24 days, followed by 4 white "reminder" pills (without hormones) to be taken for four days.

3. ALSO FIND:

- 1) Where on the pack to start taking pills,
- 2) In what order to take the pills (follow the arrows)
- 3) The week numbers as shown in the diagram below

START

Monday Tuesday Wednesday Thursday Friday Saturday Sunday



YAZ Tablets

(drospirenone and ethinyl estradiol)

4. BE SURE YOU HAVE READY AT ALL TIMES:

ANOTHER KIND OF BIRTH CONTROL (such as condoms or spermicides) to use as a back-up in case you miss pills.

AN EXTRA, FULL PILL PACK.

WHEN TO START THE *FIRST* PACK OF PILLS

You have a choice for which day to start taking your first pack of pills. Decide with your healthcare provider which is the best day for you. Pick a time of day which will be easy to remember.

DAY 1 START:

- 1. Take the first light pink "active" pill of the first pack during the *first 24 hours of your period*.

2. You will not need to use a back-up method of birth control, since you are starting the pill at the beginning of your period.

SUNDAY START:

1. Take the first light pink "active" pill of the first pack on the *Sunday after your period starts*, even if you are still bleeding. If your period begins on Sunday, start the pack that same day.
2. *Use another method of birth control* (such as condoms or spermicides) as a back-up method if you have sex anytime from the Sunday you start your first pack until the next Sunday (7 days).

WHEN YOU SWITCH FROM A DIFFERENT BIRTH CONTROL PILL

When switching from another birth control pill, YAZ should be started on the same day that a new pack of the previous birth control pills would have been started.

WHAT TO DO DURING THE MONTH

1. TAKE ONE PILL AT THE SAME TIME EVERY DAY UNTIL THE PACK IS EMPTY

Do not skip pills even if you are spotting or 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 OF PILLS:

Start the next pack on the day after your last white "reminder" pill. Do not wait any days between packs.

WHAT TO DO IF YOU MISS PILLS

If you **MISS 1** light pink "active" pill in Week 1 of your pack:

1. Take it as soon as you remember. Take the next pill at your regular time. This means you may take two pills in one day.
2. You do not need to use a back-up birth control method if you have sex.

If you **MISS 2** light pink "active" pills in a row in **WEEK 1** or **WEEK 2** of your pack:

1. Take two pills on the day you remember and two pills the next day.
2. Then take one pill a day until you finish the pack.
3. You **COULD BECOME PREGNANT** if you have sex in the *7 days* after you restart your pills. You **MUST** use another birth control method (such as condoms or spermicides) as a back-up for those 7 days.

If you **MISS 2** light pink "active" pills in a row in **WEEK 3** or **Week 4** of your pack:

1. If you are a Day 1 Starter:

THROW OUT the rest of the pill pack and start a new pack that same day.

If you are a Sunday Starter:

Keep taking one pill every day until Sunday. On Sunday, THROW OUT the rest of the pack and start a new pack of pills that same day.

2. You COULD BECOME PREGNANT if you have sex in the 7 days after you restart your pills. You MUST use another birth control method (such as condoms or spermicides) as a back-up for those 7 days.
3. You may not have your period this month but this is expected. However, if you miss your period two months in a row, call your healthcare provider because you might be pregnant.

If you **MISS 3 OR MORE** light pink "active" pills in a row during **ANY Week**:

1. **If you are a Day 1 Starter:**

THROW OUT the rest of the pill pack and start a new pack that same day.

If you are a Sunday Starter:

Keep taking 1 pill every day until Sunday. On Sunday, THROW OUT the rest of the pack and start a new pack of pills that same day.

2. You COULD BECOME PREGNANT if you have sex in the 7 days after you restart pills. You MUST use another birth control method (such as condoms or spermicides) as a back-up for those 7 days.
3. You may not have your period this month but this is expected. However, if you miss your period two months in a row, call your healthcare provider because you might be pregnant.

If you **MISS ANY** of the 4 **white** "reminder" pills in **Week 4**:

THROW AWAY the pills you missed.

Keep taking one pill each day until the pack is empty.

You do not need a back-up method of birth control.

FINALLY, IF YOU ARE STILL NOT SURE WHAT TO DO ABOUT THE PILLS YOU HAVE MISSED:

Use a BACK-UP METHOD (such as condoms or spermicides) anytime you have sex.

KEEP TAKING ONE ACTIVE LIGHT PINK PILL EACH DAY until you can contact your healthcare provider.

For additional information see "Detailed Patient Labeling"

DETAILED PATIENT PACKAGE INSERT

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YAZ is different from other birth-control pills because it contains the progestin drospirenone. Drospirenone may increase potassium. Therefore, you should not take YAZ if you have kidney, liver or adrenal disease because this could cause serious heart and health problems. Other

drugs may also increase potassium. If you are currently on daily, long-term treatment for a chronic condition with any of the medications below, you should consult your healthcare provider about whether YAZ is right for you, and during the first month that you take YAZ, you should have a blood test to check your potassium level.

- **NSAIDs (ibuprofen [Motrin, Advil], naprosyn [Aleve and others] when taken long-term and daily for treatment of arthritis or other problems)**
- **Potassium-sparing diuretics (spironolactone and others)**
- **Potassium supplementation**
- **ACE inhibitors (Capoten, Vasotec, Zestril and others)**
- **Angiotensin-II receptor antagonists (Cozaar, Diovan, Avapro and others)**
- **Heparin**
- **Aldosterone antagonists**

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YAZ may also be taken to treat premenstrual dysphoric disorder (PMDD) if you choose to use the Pill for birth control. Unless you have already decided to use the Pill for birth control, you should not start YAZ to treat your PMDD because there are other medical therapies for PMDD that do not have the same risks as the Pill. PMDD is a mood disorder related to the menstrual cycle. PMDD significantly interferes with work or school, or with usual social activities and relationships with others. Symptoms include markedly depressed mood, anxiety or tension, mood swings, and persistent anger or irritability. Other features include decreased interest in usual activities, difficulty concentrating, lack of energy, change in appetite or sleep, and feeling out of control. Physical symptoms associated with PMDD may include breast tenderness, headache, joint and muscle pain, bloating and weight gain. These symptoms occur regularly before menstruation starts and go away within a few days following the start of the period. Diagnosis of PMDD should be made by healthcare providers.

You should only use YAZ for treatment of PMDD if you:

- Have already decided to use oral contraceptives for birth control, and
- Have been diagnosed with PMDD by your healthcare provider.

YAZ has not been shown to be effective for the treatment of premenstrual syndrome (PMS), a less serious cluster of symptoms occurring before menstruation. If you or your healthcare provider believes you have PMS, you should only take YAZ if you want to prevent pregnancy; and not for the treatment of PMS.

YAZ may also be taken to treat moderate acne in women who are able to and wish to use the pill for birth control.

INTRODUCTION

Any woman who needs contraception (birth control) and chooses to use an oral contraceptive should understand the benefits and risks of using the Pill. This leaflet will give you much of the information you will need to help you decide if you should use the Pill for contraception and will also help you determine if you are at risk of developing any of the serious side effects of the Pill. It will tell you how to use the Pill properly so that it will be as effective as possible. However, this leaflet is not a replacement for a careful discussion between you and your healthcare professional. You should discuss the information provided in this leaflet with him or her, both when you first start taking the Pill and during your revisits. You should also follow your healthcare professional's advice with regard to regular check-ups while you are on the Pill.

EFFECTIVENESS OF YAZ FOR PREVENTION OF PREGNANCY

Oral contraceptives or "birth-control pills" or "the Pill" are used to prevent pregnancy and are more effective than most other nonsurgical methods of birth control. When they are taken correctly, the chance of becoming pregnant is less than 1.0% (one pregnancy per 100 women per year of use) when used perfectly, without missing any pills. Typical failure rates, including women who don't always follow the instructions exactly, are about 5% per year. The chance of becoming pregnant increases with each missed pill during a menstrual cycle.

In comparison, typical failure rates for other nonsurgical methods of birth control during the first year of use are as follows:

Percentage of women experiencing an unintended pregnancy during the first year of typical use and first year of perfect use of contraception and the percentage continuing use at the end of the first year: United States.

Method (1)	% of Women Experiencing an Unintended Pregnancy within the First Year of Use		% of Women Continuing Use at One Year ³ (4)
	Typical Use ¹ (2)	Perfect Use ² (3)	
Chance ⁴	85	85	
Spermicides ⁵	26	6	40
Periodic abstinence	25		63
Calendar		9	
Ovulation method		3	
Sympto-thermal ⁶		2	
Post-ovulation		1	
Withdrawal	19	4	
Cap ⁷			
Parous women	40	26	42
Nulliparous women	20	9	56
Sponge			
Parous women	40	20	42
Nulliparous women	20	9	56
Diaphragm ⁷	20	6	56
Condom ⁸			
Female (Reality)	21	5	56
Male	14	3	61
Pill	5		71
progestin only		0.5	
combined		0.1	
IUD:			
Progesterone T	2	1.5	81
Copper T 380A	0.8	0.6	78
Lng 20	0.1	0.1	81
Depo Provera	0.3	0.3	70
Norplant and Norplant-2	0.05	0.05	88
Female sterilization	0.5	0.5	100
Male sterilization	0.15	0.1	100

Emergency Contraceptive Pills: Treatment initiated within 72 hours after unprotected intercourse reduces the risk of pregnancy by at least 75%.⁹

Lactational Amenorrhea Method: LAM is a highly effective, *temporary* method of contraception.¹⁰

Source: Trussell J, Contraceptive efficacy. In Hatcher RA, Trussell J, Stewart F, Cates W, Stewart GK, Guest F, Kowal D, Contraceptive Technology: Seventeenth Revised Edition. New York NY: Irvington Publishers, 1998.

- 1 Among typical couples who initiate use of a method (not necessarily for the first time), the percentage who experience an accidental pregnancy during the first year if they do not stop use for any other reason.
- 2 Among couples who initiate use of a method (not necessarily for the first time) and who use it perfectly (both consistently and correctly). The percentage who experience an accidental pregnancy during the first year if they do not stop use for any reason.
- 3 Among couples attempting to avoid pregnancy, the percentage who continue to use a method for one year.
- 4 The percents becoming pregnant in columns (2) and (3) are based on data from populations where contraception is not used and from women who cease using contraception in order to become pregnant. Among such populations, about 89% become pregnant within one year. This estimate was lowered slightly (to 85%) to represent the percentage who would become pregnant within one year among women now relying on reversible methods of contraception if they abandoned contraception altogether.
- 5 Foams, creams, gels vaginal suppositories, and vaginal film.
- 6 Cervical mucus (ovulation) method supplemented by calendar in the pre-ovulatory and basal body temperature in the post-ovulatory phases.
- 7 With spermicidal cream or jelly
- 8 Without spermicides.
- 9 The treatment schedule is one dose within 72 hours after unprotected intercourse, and a second dose 12 hours after the first dose. The Food and Drug Administration has declared the following brands of oral contraceptives to be safe and effective for

- 10 emergency contraception: Ovral (1 dose is 2 white pills), Alesse (1 dose is 5 pink pills), Nordette or Levlen (1 dose is 2 light-orange pills), Lo/Ovral (1 dose is 4 white pills), Triphasil or Tri-Levlen (1 dose is 4 yellow pills).
However, to maintain effective protection against pregnancy, another method of contraception must be used as soon as menstruation resumes, the frequency or duration of breastfeeds is reduced, bottle feeds are introduced, or the baby reaches six months of age.

YAZ may also be taken to treat moderate acne if **all** of the following are true:

- Your doctor says it is safe for you to use the pill.
- You are at least 14 years old.
- You have started having menstrual periods.
- You want to use the pill for birth control

WHO SHOULD NOT TAKE YAZ or ORAL CONTRACEPTIVES

Cigarette smoking increases the risk of serious adverse effects on the heart and blood vessels from oral contraceptive use. This risk increases with age and with heavy smoking (15 or more cigarettes per day) and is quite marked in women over 35 years of age. Women who use oral contraceptives should not smoke.

Some women should not use YAZ. For example, you should not take YAZ if you are pregnant or think you may be pregnant. You should also not use YAZ if you have had any of the following conditions:

- A history of heart attack or stroke
- A history of blood clots in the legs (deep vein thrombosis), lungs (pulmonary embolism), or eyes (retinal thrombosis)
- Chest pain (angina pectoris)
- Known or suspected breast cancer or cancer of the lining of the uterus, cervix or vagina
- Unexplained vaginal bleeding (until a diagnosis is reached by your doctor)
- Yellowing of the whites of the eyes or of the skin (jaundice) during pregnancy or during previous use of the pill or other hormonal contraceptives
- Liver tumor (benign or cancerous)
- Known or suspected pregnancy
- Heart valve or heart rhythm disorders that may be associated with formation of blood clots
- Diabetes with complications of the kidneys, eyes, nerves, or blood vessels
- Severe high blood pressure
- A need for surgery with prolonged bedrest
- Headaches with neurological symptoms
- Allergy or hypersensitivity to any of the components of YAZ

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

- Kidney Disease
- Liver Disease
- Adrenal Disease

Tell your healthcare provider if you have ever had any of the above conditions (Your healthcare provider can recommend another method of birth control). If you are currently on daily, long-term treatment for a chronic condition with any of the following medications, you should consult your healthcare provider before taking YAZ:

- NSAIDs (ibuprofen, naprosyn and others)
- Potassium-sparing diuretics (spironolactone and others)
- Potassium supplementation
- ACE inhibitors (captopril, enalapril, lisinopril and others)
- Angiotensin-II receptor antagonists (Cozaar, Diovan, Avapro and others)
- Heparin
- Aldosterone antagonists

OTHER CONSIDERATIONS BEFORE TAKING ORAL CONTRACEPTIVES

Tell your healthcare provider if you have or ever had:

- Breast nodules, fibrocystic disease of the breast, an abnormal breast X-ray or mammogram
- Diabetes
- Elevated cholesterol or triglycerides
- High blood pressure
- A blood test indicating a higher risk of having blood clots
- Migraine or other headaches or epilepsy
- Mental depression
- Gallbladder, heart or kidney disease
- History of scanty or irregular menstrual periods

Women with any of these conditions should be checked often by their healthcare provider if they choose to use oral contraceptives.

Also, be sure to inform your doctor or healthcare provider if you smoke, are on any medications, recently had a baby or miscarriage, or are breast feeding.

RISKS OF TAKING ORAL CONTRACEPTIVES

1. RISK OF DEVELOPING BLOOD CLOTS

Blood clots and blockage of blood vessels are the most serious side effects of taking oral contraceptives and can be fatal. In particular, a clot in the legs (deep vein thrombosis) can cause pain and swelling, and a clot that travels to the lungs can cause sudden blocking of the vessel carrying blood to the lungs. Rarely, clots occur in the blood vessels of the eye and may cause blindness, double vision, or impaired vision.

If you take oral contraceptives and need elective surgery, need to stay in bed for a prolonged illness or have recently delivered a baby, you may be at risk of developing blood clots. You should consult your doctor about stopping oral contraceptives three to four weeks before surgery and not taking oral contraceptives for two weeks after surgery or during bed rest. You should also not take oral contraceptives soon after delivery of a baby or a mid-trimester pregnancy loss or termination. It is advisable to wait for at least four to six weeks after delivery if you are not breast-feeding. If you are breast-feeding, you should wait until you have weaned your child before using the pill. (See also the section on breast-feeding in **GENERAL PRECAUTIONS.**)

2. HEART ATTACKS AND STROKES

Oral contraceptives may increase the tendency to develop strokes (stoppage or rupture of blood vessels in the brain) and angina pectoris and heart attacks (blockage of blood vessels in the heart). Any of these conditions can cause death or serious disability.

Smoking greatly increases the possibility of suffering heart attacks and strokes. Furthermore, smoking and the use of oral contraceptives greatly increase the chances of developing and dying of heart disease.

3. GALLBLADDER DISEASE

Oral contraceptive users probably have a greater risk than nonusers of having gallbladder disease, although this risk may be related to pills containing high doses of estrogens.

4. LIVER TUMORS

In rare cases, oral contraceptives can cause benign but dangerous liver tumors. These benign liver tumors can rupture and cause fatal internal bleeding. In addition, a possible but not definite association has been found with the pill and liver cancers in two studies, in which a few women who developed these very rare cancers were found to have used oral contraceptives for long periods. However, liver cancers are extremely rare. The chance of developing liver cancer from using the pill is thus even rarer.

5. CANCER OF THE REPRODUCTIVE ORGANS AND BREASTS

Various studies give conflicting reports on the relationship between breast cancer and oral contraceptive use. Oral contraceptive use may slightly increase your chance of having breast cancer diagnosed, particularly after using hormonal contraceptives at a younger age. After you stop using hormonal contraceptives, the chances of getting breast cancer begin to go back down. You should have regular breast examinations by a healthcare provider and examine your own breasts monthly. Tell your healthcare provider if you have a family history of breast cancer or if you have had breast nodules or an abnormal mammogram. Women who currently have or have had breast cancer should not use oral contraceptives because breast cancer is a hormone-sensitive tumor.

Some studies have found an increase in the incidence of cancer of the cervix in women who use oral contraceptives. However, this finding may be related to factors other than the use of oral contraceptives.

ESTIMATED RISK OF DEATH FROM A BIRTH-CONTROL METHOD OR PREGNANCY

All methods of birth control and pregnancy are associated with a risk of developing certain diseases which may lead to disability or death. An estimate of the number of deaths associated with different methods of birth control and pregnancy has been calculated and is shown in the following table.

ANNUAL NUMBER OF BIRTH-RELATED OR METHOD-RELATED DEATHS ASSOCIATED WITH CONTROL OF FERTILITY PER 100,000 NONSTERILE WOMEN, BY FERTILITY-CONTROL METHOD ACCORDING TO AGE

Method of Control and Outcome	15-19 years	20-24 years	25-29 years	30-34 years	35-39 years	40-44 years
No fertility control methods\1\	7	7.4	9.1	14.8	25.7	28.2
Oral contraceptives non-smoker \2\	0.3	0.5	0.9	1.9	13.8	31.6
Oral contraceptives smoker \2\	2.2	3.4	6.6	13.5	51.1	117.2
IUD \2\	0.8	0.8	1	1	1.4	1.4
Condom \1\	1.1	1.6	0.7	0.2	0.3	0.4
Diaphragm/spermicide \1\	1.9	1.2	1.2	1.3	2.2	2.8
Periodic abstinence \1\	2.5	1.6	1.6	1.7	2.9	3.6

\1\ Deaths are birth related

\2\ Deaths are method related

Adapted from H.W. Ory, Family Planning Perspectives, 15:57-63, 1983.

In the above table, the risk of death from any birth-control method is less than the risk of childbirth, except for oral contraceptive users over the age of 35 who smoke and pill users over the age of 40 even if they do not smoke. It can be seen in the table that for women aged 15 to 39, the risk of death was highest with pregnancy (7-26 deaths per 100,000 women, depending on age). Among pill users who do not smoke, the risk of death was always lower than that associated with pregnancy for any age group, except for those women over the age of 40, when the risk increases to 32 deaths per 100,000 women, compared to 28 associated with pregnancy at that age. However, for pill users who smoke and are over the age of 35, the estimated number of deaths exceeds those for other methods of birth control. If a woman is over the age of 40 and smokes, her estimated risk of death is four times higher (117/100,000 women) than the estimated risk associated with pregnancy (28/100,000 women) in that age group.

The suggestion that women over 40 who do not smoke should not take oral contraceptives is based on information from older high-dose pills and on less-selective use of pills than is practiced today. An Advisory Committee of the FDA discussed this issue in 1989 and recommended that the benefits of oral contraceptive use by healthy, non-smoking women over 40 years of age may outweigh the possible risks. However, all women, especially older women, are cautioned to use the lowest-dose pill that is effective.

WARNING SIGNALS

If any of these adverse effects occur while you are taking oral contraceptives, call your doctor immediately:

- Sharp chest pain, coughing of blood, or sudden shortness of breath (indicating a possible clot in the lung)
- Pain in the calf (indicating a possible clot in the leg)
- Crushing chest pain or heaviness in the chest (indicating a possible heart attack)
- Sudden severe headache or vomiting, dizziness or fainting, disturbances of vision or speech, weakness, or numbness in an arm or leg (indicating a possible stroke)
- Sudden partial or complete loss of vision (indicating a possible clot in the eye)
- Breast lumps (indicating possible breast cancer or fibrocystic disease of the breast; ask your doctor or healthcare provider to show you how to examine your breasts)
- Severe pain or tenderness in the stomach area (indicating a possibly ruptured liver tumor)
- Difficulty in sleeping, weakness, lack of energy, fatigue, or change in mood (possibly indicating severe depression)
- Jaundice or a light yellowing of the skin or eyeballs, accompanied frequently by fever, fatigue, loss of appetite, dark-colored urine, or light-colored bowel movements (indicating possible liver problems)

SIDE EFFECTS OF ORAL CONTRACEPTIVES

1. VAGINAL BLEEDING

Irregular vaginal bleeding or spotting may occur while you are taking the pills. Irregular bleeding may vary from slight staining between menstrual periods to breakthrough bleeding, which is a flow much like a regular period. Irregular bleeding occurs most often during the first few months of oral contraceptive use, but may also occur after you have been taking the pill for some time. Such bleeding may be temporary and usually does not indicate any serious problems. It is important to continue taking your pills on schedule. If the bleeding occurs in more than one cycle or lasts for more than a few days, talk to your doctor or healthcare provider.

2. CONTACT LENSES

If you wear contact lenses and notice a change in vision or an inability to wear your lenses, contact your doctor or healthcare provider.

3. FLUID RETENTION

Oral contraceptives may cause edema (fluid retention) with swelling of the fingers or ankles and may raise your blood pressure. If you experience fluid retention, contact your doctor or healthcare provider.

4. MELASMA

A spotty darkening of the skin is possible, particularly of the face.

5. OTHER SIDE EFFECTS

Other side effects may include nausea, vomiting, change in appetite, headache, nervousness, depression, dizziness, loss of scalp hair, rash, and vaginal infections.

If any of these side effects bother you, call your doctor or healthcare provider.

GENERAL PRECAUTIONS

1. Missed periods and use of oral contraceptives before or during early pregnancy.

There may be times when you may not menstruate regularly after you have completed taking a cycle of pills. If you have taken your pills regularly and miss one menstrual period, continue taking your pills for the next cycle but be sure to inform your healthcare provider. If you have not taken the pills daily as instructed and missed a menstrual period, or if you missed two consecutive menstrual periods, you may be pregnant. Check with your healthcare provider immediately to determine whether you are pregnant. Stop taking oral contraceptives if pregnancy is confirmed. There is no conclusive evidence that oral contraceptive use is associated with an increase in birth defects when taken inadvertently during early pregnancy. Previously, a few studies had reported that oral contraceptives might be associated with birth defects, but these studies have not been confirmed. Nevertheless, oral contraceptives should not be used during pregnancy. You should check with your doctor about risks to your unborn child of any medication taken during pregnancy.

2. While Breast-Feeding

If you are breast-feeding, consult your doctor before starting oral contraceptives. Some of the drug will be passed on to the child in the milk. A few adverse effects on the child have been reported, including light yellowing of the skin (jaundice) and breast enlargement. In addition, oral contraceptives may decrease the amount and quality of your milk. If possible, do not use oral contraceptives while breast-feeding. You should use another method of contraception since breast-feeding provides only partial protection from becoming pregnant, and this partial protection decreases significantly as you breast-feed for longer periods of time. You should consider starting oral contraceptives only after you have weaned your child completely.

3. Laboratory Tests

If you are scheduled for any laboratory tests, tell your doctor you are taking birth-control pills. Certain blood tests may be affected by birth-control pills.

4. Drug Interactions

Certain drugs may interact with birth-control pills to make them less effective in preventing pregnancy or cause an increase in breakthrough bleeding. Such drugs include rifampin, drugs used for epilepsy such as barbiturates (for example, phenobarbital) and phenytoin (Dilantin is one brand of this drug), phenylbutazone (Butazolidin is one brand) and possibly certain antibiotics. Herbal products containing St. John's Wort (*hypericum perforatum*) may reduce the effectiveness of oral contraceptives. This may also result in breakthrough bleeding. You may need to use an additional method of contraception during any cycle in which you take drugs that can make oral contraceptives less effective (**See BOLDDED TEXT AT BEGINNING**).

5. Sexually transmitted diseases

This product (like all oral contraceptives) is intended to prevent pregnancy. It does not protect against transmission of HIV (AIDS) and other sexually transmitted diseases such as chlamydia, genital herpes, genital warts, gonorrhea, hepatitis B, and syphilis.

INSTRUCTIONS TO PATIENTS

HOW TO TAKE THE PILL

IMPORTANT POINTS TO REMEMBER

BEFORE YOU START TAKING YOUR PILLS:

1. BE SURE TO READ THESE DIRECTIONS:

Before you start taking your pills.

Anytime you are not sure what to do.

2. THE RIGHT WAY TO TAKE THE PILL IS TO TAKE ONE PILL EVERY DAY AT THE SAME TIME. YAZ CAN BE TAKEN WITHOUT REGARD TO MEALS.

If you miss pills you could get pregnant. This includes starting the pack late. The more pills you miss, the more likely you are to get pregnant. See “**WHAT TO DO IF YOU MISS PILLS**” below.

3. MANY WOMEN HAVE SPOTTING OR LIGHT BLEEDING, OR MAY FEEL SICK TO THEIR STOMACH DURING THE FIRST 1-3 PACKS OF PILLS.

If you do have spotting or light bleeding or feel sick to your stomach, do not stop taking the pill. The problem will usually go away. If it does not go away, check with your healthcare provider.

4. MISSING PILLS CAN ALSO CAUSE SPOTTING OR LIGHT BLEEDING, even when you make up these missed pills.

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

5. IF YOU HAVE VOMITING (within 3 to 4 hours after you take your pill), you should follow the instructions for “**WHAT TO DO IF YOU MISS PILLS**”. IF YOU HAVE DIARRHEA or IF YOU TAKE CERTAIN MEDICINES, including some antibiotics and some herbal products such as St. John’s Wort, your pills may not work as well.

Use a back-up method (such as condoms or spermicides) until you check with your healthcare provider.

6. IF YOU HAVE TROUBLE REMEMBERING TO TAKE THE PILL, talk to your healthcare provider about how to make pill-taking easier or about using another method of birth control.

7. IF YOU HAVE ANY QUESTIONS OR ARE UNSURE ABOUT THE INFORMATION IN THIS LEAFLET, call your healthcare provider.

BEFORE YOU START TAKING YOUR PILLS

1. DECIDE WHAT TIME OF DAY YOU WANT TO TAKE YOUR PILL.

It is important to take YAZ at about the same time every day. YAZ can be taken without regard to meals.

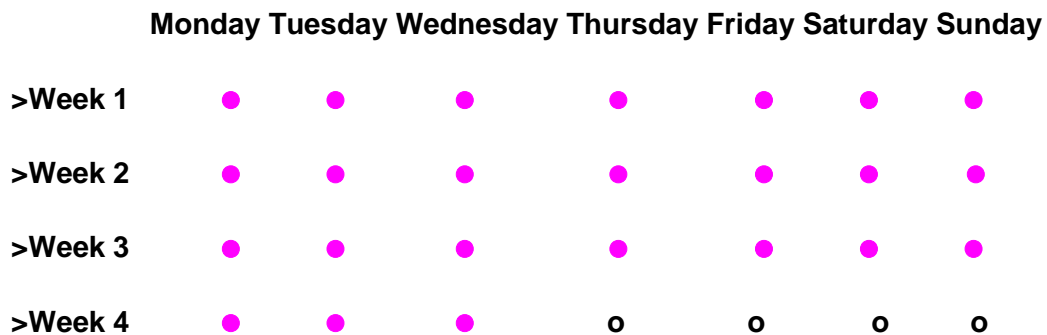
2. LOOK AT YOUR PILL PACK: – IT HAS 28 PILLS

The YAZ-*pill pack* has 24 light pink "active" pills (with hormones) to be taken for 24 days, followed by 4 white "reminder" pills (without hormones) to be taken for four days.

3. ALSO FIND:

- 1) Where on the pack to start taking pills,
- 2) In what order to take the pills (follow the arrows)
- 3) The week numbers as shown in the diagram below

START



YAZ Tablets

(drospirenone and ethinyl estradiol)

4. BE SURE YOU HAVE READY AT ALL TIMES:

ANOTHER KIND OF BIRTH CONTROL (such as condoms or spermicides) to use as a back-up in case you miss pills.

AN EXTRA, FULL PILL PACK.

WHEN TO START THE *FIRST* PACK OF PILLS

You have a choice for which day to start taking your first pack of pills. Decide with your healthcare provider which is the best day for you. Pick a time of day which will be easy to remember.

DAY 1 START:

1. Take the first light pink "active" pill of the first pack during the *first 24 hours of your period*.
2. You will not need to use a back-up method of birth control, since you are starting the pill at the beginning of your period.

SUNDAY START:

1. Take the first light pink "active" pill of the first pack on the *Sunday after your period starts*, even if you are still bleeding. If your period begins on Sunday, start the pack that same day.
2. *Use another method of birth control* (such as condoms or spermicides) as a back-up method if you have sex anytime from the Sunday you start your first pack until the next Sunday (7 days).

WHEN YOU SWITCH FROM A DIFFERENT BIRTH CONTROL PILL

When switching from another birth control pill, YAZ should be started on the same day that a new pack of the previous birth control pill would have been started.

WHAT TO DO DURING THE MONTH

1. TAKE ONE PILL AT THE SAME TIME EVERY DAY UNTIL THE PACK IS EMPTY

Do not skip pills even if you are spotting or 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 OF PILLS:

Start the next pack on the day after your last white "reminder" pill. Do not wait any days between packs.

WHAT TO DO IF YOU MISS PILLS

If you **MISS 1** light pink "active" pill:

1. Take it as soon as you remember. Take the next pill at your regular time. This means you may take two pills in one day.
2. You do not need to use a back-up birth control method if you have sex.

If you **MISS 2** light pink "active" pills in a row in **WEEK 1 OR WEEK 2** of your pack:

1. Take two pills on the day you remember and two pills the next day.
2. Then take one pill a day until you finish the pack.
3. You **COULD BECOME PREGNANT** if you have sex in the *7 days* after you restart your pills. You **MUST** use another birth control method (such as condoms or spermicides) as a back-up for those 7 days.

If you **MISS 2** light pink "active" pills in a row in **WEEK 3** or **Week 4** of your pack:

1. If you are a Day 1 Starter:

THROW OUT the rest of the pill pack and start a new pack that same day.

If you are a Sunday Starter:

Keep taking one pill every day until Sunday. On Sunday, THROW OUT the rest of the pack and start a new pack of pills that same day.

2. You **COULD BECOME PREGNANT** if you have sex in the *7 days* after you restart your pills. You **MUST** use another birth control method (such as condoms or spermicide) as a back-up for those 7 days.
3. You may not have your period this month but this is expected. However, if you miss your period two months in a row, call your doctor or clinic because you might be pregnant.

If you **MISS 3 OR MORE** light pink "active" pills in a row during **ANY Week**:

1. **If you are a Day 1 Starter:**

THROW OUT the rest of the pill pack and start a new pack that same day.

If you are a Sunday Starter:

Keep taking 1 pill every day until Sunday. On Sunday, THROW OUT the rest of the pack and start a new pack of pills that same day.

2. You COULD BECOME PREGNANT if you have sex in the 7 days after you restart your pills. You MUST use another birth control method (such as condoms or spermicides) as a back-up for those 7 days.
3. You may not have your period this month but this is expected. However, if you miss your period two months in a row, call your doctor or clinic because you might be pregnant.

If you **MISS ANY** of the 4 **white** "reminder" pills in **Week 4**:

THROW AWAY the pills you missed.

Keep taking one pill each day until the pack is empty.

You do not need a back-up method.

FINALLY, IF YOU ARE STILL NOT SURE WHAT TO DO ABOUT THE PILLS YOU HAVE MISSED:

Use a BACK-UP METHOD (such as condoms or spermicides) anytime you have sex.

KEEP TAKING ONE ACTIVE LIGHT PINK PILL EACH DAY until you contact your healthcare provider.

PREGNANCY AFTER STOPPING THE PILL

There may be some delay in becoming pregnant after you stop using oral contraceptives, especially if you had irregular menstrual cycles before you used oral contraceptives. It may be advisable to postpone conception until you begin menstruating regularly once you have stopped taking the pill and desire pregnancy.

There does not appear to be any increase in birth defects in newborn babies when pregnancy occurs soon after stopping the pill.

OVERDOSAGE

Serious ill effects have not been reported following ingestion of large doses of other oral contraceptives by young children. Overdosage of YAZ may cause nausea and withdrawal bleeding in females and may increase blood levels of potassium or decrease blood levels of sodium, which could be dangerous. In case of overdosage, contact your healthcare provider.

OTHER INFORMATION

Your healthcare provider will take a medical and family history before prescribing oral contraceptives and will examine you. The physical examination may be delayed to another time if you request it and the healthcare provider believes that it is appropriate to postpone it. You should be re-examined at least once a year. Be sure to inform your healthcare provider if there is a family history of any of the

conditions listed previously in this leaflet. Be sure to keep all appointments with your healthcare provider, because this is a time to determine if there are early signs of side effects of oral contraceptive use.

Do not use the drug for any condition other than the one for which it was prescribed. This drug has been prescribed specifically for you; do not give it to others who may want birth-control pills.

HEALTH BENEFITS FROM ORAL CONTRACEPTIVES

In addition to preventing pregnancy, use of oral contraceptives may provide certain benefits. They are:

- Menstrual cycles may become more regular.
- Blood flow during menstruation may be lighter and less iron may be lost. Therefore, anemia due to iron deficiency is less likely to occur.
- Pain or other symptoms during menstruation may be encountered less frequently.
- Ovarian cysts may occur less frequently.
- Ectopic (tubal) pregnancy may occur less frequently.
- Noncancerous cysts or lumps in the breast may occur less frequently.
- Acute pelvic inflammatory disease may occur less frequently.
- Oral contraceptive use may provide some protection against developing two forms of cancer: cancer of the ovaries and cancer of the lining of the uterus.

If you want more information about birth-control pills, ask your doctor or pharmacist. They have a more technical leaflet called the Prescribing Information which you may wish to read.

Manufactured for Berlex

BERLEX, Montville, NJ 07045

Manufactured in Germany

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CODE NUMBER

DATE