



Dear Pharmacist:

On May 28, 2010, Teva Pharmaceuticals introduced Gianvi™ (drospirenone and ethinyl estradiol tablets), AB rated and bioequivalent to Yaz®* Tablets. This letter serves as notification that the Gianvi™ Physician Prescribing Information is being updated to reflect a clarification in the inactive ingredients. **Specifically, Teva's Gianvi™ product contains ethinyl estradiol which is not stabilized by betadex as a clathrate.**

The Physician Prescribing Information included with initial shipments of Gianvi™ (revision code B 4/2010) has been updated. The new Physician Prescribing Information is included below and is accessible on our website at www.tevausea.com/Gianvi_PI. For your reference, the change is highlighted below:

Original Physician Prescribing Information, Revision B 4/2010

Description: Gianvi™ (drospirenone and ethinyl estradiol tablets) 3 mg/0.02 mg provides an oral contraceptive regimen consisting of 24 active film-coated tablets each containing 3 mg of drospirenone and 0.02 mg of ethinyl estradiol stabilized by betadex as a clathrate (molecular inclusion complex) and 4 inert film-coated tablets. Other ingredients are...

Updated Physician Prescribing Information, Revision D 6/2010

Description: Gianvi™ (drospirenone and ethinyl estradiol tablets) 3 mg/0.02 mg provides an oral contraceptive regimen consisting of 24 active film-coated tablets each containing 3 mg of drospirenone and 0.02 mg of ethinyl estradiol and 4 inert film-coated tablets. Other ingredients are...

Please accept our apology for any inconvenience this may have caused. And we thank you for your continued support of Teva's products.

Sincerely,

A handwritten signature in black ink that reads "Maureen M. Cavanaugh".

Maureen M. Cavanaugh
Vice President, Customer Operations & Marketing

* Yaz® is a registered trademark of Bayer Schering Pharma.

Administrative Offices:

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HOW SUPPLIED
Gianvi™ (drospirenone and ethinyl estradiol tablets) 3 mg/0.02 mg – 28-Day Regimen are available in packages of 3 blister packs (NDC 0093-5661-58).
Each blister card contains 24 active pink, round, unscored, film-coated tablets, debossed with stylized **b** on one side and **257** on the other side, each containing 3 mg of drospirenone and 0.02 mg of ethinyl estradiol, and 4 inert white, round, unscored tablets debossed with stylized **a** on one side and **288** on the other side.
KEEP THIS AND ALL MEDICATIONS OUT OF THE REACH OF CHILDREN.
Store at 20° to 25° (68° to 77°F) [See USP Controlled Room Temperature].

REFERENCES
1. Dinger JC, Heinemann LAJ, et al: The safety of a drospirenone-containing oral contraceptive: final results from the European active surveillance study on oral contraceptives based on 142,475 women-years of observation. *Contraception* 2007;75:344-354.
2. Seeger JD, Loughlin J, Eng PM, et al: Risk of thromboembolism in women taking ethinyl estradiol/drospirenone and other oral contraceptives. *Obstetrics & Gynecology* 2007;110(3):587-593.
3. van Hylckama Vlieg A, Heinemorst FM, Vandenbroucke JP, et al: The venous thrombotic risk of oral contraceptives, effects of estrogen dose and progestogen type: results of the MEGA case-control study. *BMJ* 2009;339:92921.
4. Lidegaard O, Lokegaard A, Svendsen AL, et al: Hormonal contraception and risk of venous thromboembolism: national follow-up study. *BMJ* 2009; 339:b2890.
BRIEF SUMMARY PATIENT PACKAGE INSERT
Gianvi™ (drospirenone and ethinyl estradiol tablets) containing the following:
24 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.

Gianvi™ (drospirenone and ethinyl estradiol tablets) is different from other birth control pills because it contains the progestin drospirenone. Drospirenone may increase potassium. Therefore, you should not take drospirenone and ethinyl estradiol tablets if you have kidney, liver or adrenal disease because this could cause serious heart and health problems.
• Do not take drospirenone and ethinyl estradiol tablets 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 drospirenone and ethinyl estradiol tablets is right for you, and during the first month that you take drospirenone and ethinyl estradiol tablets, you should have blood tests to check your potassium level.
• NSAIDs (ibuprofen [Motrin®, Advil®], naproxen [Aleve® and others] when taken long-term and daily for treatment of arthritis or other problems)
• Potassium-sparing diuretics (spironolactone and others)
• ACE inhibitors (Capoten®, Vasotec®, Zestril® and others)
• Angiotensin-II receptor antagonists (Cozaar®, Diovan®, Avapro® and others)
• Heparin
• Aldosterone antagonists

Gianvi™ (drospirenone and ethinyl estradiol tablets) 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.
Gianvi™ (drospirenone and ethinyl estradiol tablets) 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 understand 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.
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 are:

- 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 are pregnant or 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 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 re-examined at least once a year while taking oral contraceptive. 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.

DETAILED PATIENT PACKAGE INSERT
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.

Gianvi™ (drospirenone and ethinyl estradiol tablets) is different from other birth control pills because it contains the progestin drospirenone. Drospirenone may increase potassium. Therefore, you should not take drospirenone and ethinyl estradiol tablets 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 drospirenone and ethinyl estradiol tablets is right for you, and during the first month that you take drospirenone and ethinyl estradiol tablets, you should have a blood test to check your potassium level.
• NSAIDs (ibuprofen [Motrin®, Advil®], naproxen [Aleve® and others] when taken long-term and daily for treatment of arthritis or other problems)
• Potassium-sparing diuretics (spironolactone and others)
• ACE inhibitors (Capoten®, Vasotec®, Zestril® and others)
• Angiotensin-II receptor antagonists (Cozaar®, Diovan®, Avapro® and others)
• Heparin
• Aldosterone antagonists

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 TO 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 Gianvi tablets at about the same time every day. Gianvi tablets can be taken without regard to meals.
2. LOOK AT YOUR PILL PACK—IT HAS 28 PILLS:
The Gianvi tablets-pill pack has 24 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 are shown on the blister card picture below

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 PROBABLY PERCENTAGE OF WOMEN EXPERIENCING AN UNINTENDED PREGNANCY DURING THE FIRST YEAR OF TYPICAL USE AT THE END OF THE FIRST YEAR, UNITED STATES.

Method (1)	% of Women Experiencing an Unintended Pregnancy Within the First Year of Use Typical Use ¹ (2)	Perfect Use ² (3)	% of Women Continuing Use at One Year ³ (4)
Chance ⁴	85	85	
Spermicides ⁵	26	6	40
Periodic abstinence	26	9	63
Calendar			
Ovulation method		3	
Sympto-therm ⁶		2	
Post-ovulation		1	
Withdrawal	19	4	100
Cap ⁷			
Parous women	40	26	42
Nulliparous women	20	9	56
Sponge			
Parous women	40	20	42
Nulliparous women	20	9	56
Diaphragm ⁸	20	6	56
Condom ⁹			
Female (Reality)	21	5	56
Male	14	3	61
Pill	5		71

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 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 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 3 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.
2. 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.
3. 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.

Emergency Contraceptive Pills: Treatment initiated within 72 hours after unprotected intercourse reduces the risk of pregnancy by at least 75%.
Lactational Amenorrhea Method: LAM is 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: Irving Publications, 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 they do not stop use for any 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 emergency contraception: Ovral (1 dose is 2 white pills), Aleve (1 dose is 2 pink pills), Norleto (1 dose is 2 light-orange pills), Lo/Ovral (1 dose is 4 white pills), Triphasil or Tri-Leven (1 dose is 4 yellow pills).
10. However, to maintain effective protection against pregnancy, the 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.

Gianvi™ (drospirenone and ethinyl estradiol tablets) 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 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 Gianvi tablets. For example, you should not take Gianvi tablets if you are pregnant or think you may be pregnant. You should also not use Gianvi tablets 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).
• Kidney or suspected pregnancy that may be associated with formation of blood clots.
• 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 drospirenone and ethinyl estradiol tablets.
In addition, you should not use Gianvi tablets if you have any of the following conditions:
1. Risk of Developing Blood Clots
• Potassium-sparing diuretics (spironolactone and others)
• ACE inhibitors (captopril, enalapril, lisinopril and others)
• Angiotensin-II receptor antagonists (Cozaar®, Diovan®, Avapro® and others)
• Heparin
• Aldosterone antagonists
2. Heart Attacks and Strokes
• Potassium-sparing diuretics (spironolactone and others)
• ACE inhibitors (captopril, enalapril, lisinopril and others)
• Angiotensin-II receptor antagonists (Cozaar®, Diovan®, Avapro® and others)
• Heparin
• Aldosterone antagonists
3. Gallbladder Disease
• Potassium-sparing diuretics (spironolactone and others)
• ACE inhibitors (captopril, enalapril, lisinopril and others)
• Angiotensin-II receptor antagonists (Cozaar®, Diovan®, Avapro® and others)
• Heparin
• Aldosterone antagonists
4. 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 blockage of the vessel carrying blood to the lungs. Rarely, clots in the blood vessels of the eye 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 contraceptives may increase the risk of gallbladder disease, although this risk may be related to pills containing high doses of estrogen.

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
The overall risks 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 to 19 years	20 to 24 years	25 to 29 years	30 to 34 years	35 to 39 years	40 to 44 years
No fertility control methods ^{1\1}						
1. With spermicidal cream or jelly ²	0.3	7.4	9.1	14.8	25.7	28.2
2. Without spermicides ³	0.3	7.4	9.1	14.8	25.7	28.2
3. Oral contraceptives non-smoker ⁴	0.3	7.4	9.1	14.8	25.7	28.2
4. Oral contraceptives smoker ^{4\2}	2.2	3.4	6.6	13.5	51.1	117.2
5. IUD ^{5\1}	0.8	0.8	1	1	1.4	1.4
6. Condom ^{1\1}	1.1	1.6	0.7	0.2	0.3	0.4
7. Diaphragm/spermicide ^{1\1}	1.9	1.2	1.2	1.3	2.2	2.8
8. Periodic abstinence ^{1\1}	2.5	1.6	1.6	1.7	2.9	3.6

^{1\1} Deaths are birth-related.
² Deaths are method-related.
Adapted from H.W. Dry, *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 use.

Gianvi™ (drospirenone and ethinyl estradiol tablets) 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.

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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 Gianvi tablets. For example, you should not take Gianvi tablets if you are pregnant or think you may be pregnant. You should also not use Gianvi tablets 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).
• Kidney or suspected pregnancy that may be associated with formation of blood clots.
• 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 drospirenone and ethinyl estradiol tablets.
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Tell your healthcare provider if you have or ever had:
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• 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 blockage of the vessel carrying blood to the lungs. Rarely, clots in the blood vessels of the eye 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 contraceptives may increase the risk of gallbladder disease, although this risk may be related to pills containing high doses of estrogen.

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
The overall risks 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 to 19 years	20 to 24 years	25 to 29 years	30 to 34 years	35 to 39 years	40 to 44 years
No fertility control methods ^{1\1}						
1. With spermicidal cream or jelly ²	0.3	7.4	9.1	14.8	25.7	28.2
2. Without spermicides ³	0.3	7.4	9.1	14.8	25.7	28.2
3. Oral contraceptives non-smoker ⁴	0.3	7.4	9.1	14.8	25.7	28.2
4. Oral contraceptives smoker ^{4\2}	2.2	3.4	6.6	13.5	51.1	117.2
5. IUD ^{5\1}	0.8	0.8	1	1	1.4	1.4
6. Condom ^{1\1}	1.1	1.6	0.7	0.2	0.3	0.4
7. Diaphragm/spermicide ^{1\1}	1.9	1.2	1.2	1.3	2.2	2.8
8. Periodic abstinence ^{1\1}	2.5	1.6	1.6	1.7	2.9	3.6

^{1\1} Deaths are birth-related.
² Deaths are method-related.
Adapted from H.W. Dry, *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 use.

Gianvi™ (drospirenone and ethinyl estradiol tablets) 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 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 Gianvi tablets. For example, you should not take Gianvi tablets if you are