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**PATIENT PACKAGE INSERT BRIEF SUMMARY**  
**Cyclessa® (desogestrel/ethinyl estradiol) 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.**  
Oral contraceptives, also known as "birth control pills" or "the pill," are taken to prevent pregnancy. When taken correctly, oral contraceptives have a failure rate of about 1% per year (1 pregnancy per 100 women per year of use) when used without missing any pills. The typical failure rate of large numbers of pills is less than 5% (5 pregnancies per 100 women per year of use) when women who miss pills are included. Forgetting to take pills increases the chances of pregnancy.  
For the majority of available 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. The risks associated with taking oral contraceptives increase significantly if you:  
• smoke  
• have high blood pressure, diabetes, high cholesterol  
• have or have had clotting disorders, heart attack, stroke, angina pectoris, cancer of the breast or sex organs, jaundice, or malignancy or benign liver tumors  
You should not take the pill if you are pregnant or have unexplained vaginal bleeding. Although cardiovascular disease risks may increase with oral contraceptive use, there are also 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 cardiovascular side effects 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 are strongly advised not to smoke.**

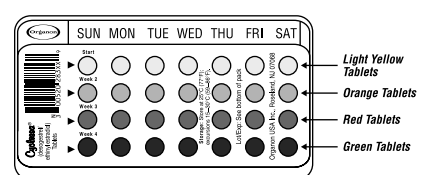
Most side effects of the pill are not serious. The most common such effects are nausea, vomiting, bleeding or spotting between menstrual periods, weight gain, breast tenderness, and difficulty wearing contact lenses. These side effects, especially nausea and vomiting, may subside within the first three months of use.  
The serious side effects of the pill occur very infrequently, especially if you are young and in good health. 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) or lungs (pulmonary embolism), stroke or rupture of a blood vessel in the brain (stroke), and blockage of blood vessels in the heart (heart attack or 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.

The symptoms associated with these serious side effects are discussed in the detailed leaflet **DETAILED PATIENT PACKAGE INSERT** 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 certain preparations containing St. John's Wort (hypericum perforatum) may decrease oral contraceptive effectiveness.  
Breast cancer has been diagnosed slightly more often in women who use the pill than in women of the same age who do not use the pill. This very small increase in the number of breast cancer diagnoses gradually disappears during the 10 years after stopping use of the pill. It is not known whether the difference is caused by the pill. It may be that women taking the pill are examined more often, so that breast cancer is more likely to be detected. 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 hormonal contraceptives because breast cancer is usually 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.  
Taking the pill provides 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 of the lining of the uterus.  
Be sure to discuss any medical condition you may have with your doctor or healthcare provider. Your doctor or healthcare provider will take a medical and family history and may examine you before prescribing oral contraceptives. The physical examination may be delayed to another time if you request it and your doctor or healthcare provider believes that it is a good medical practice to postpone it. You should be reexamined at least once a year while taking oral contraceptives. The detailed patient information leaflet gives you further information which you should read and discuss with your doctor or healthcare provider.  
**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.**

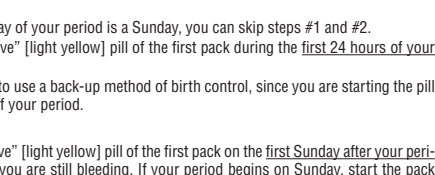
**INSTRUCTIONS TO PATIENTS**  
**HOW TO TAKE CYCLESSA®**  
Read the **IMPORTANT POINTS TO REMEMBER** in the **DETAILED PATIENT PACKAGE INSERT**.

**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.**  
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.  
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 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 doesn't go away, check with your doctor or 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 2 pills to make up for missed pills, you could also feel a little sick to your stomach.  
5. **IF YOU HAVE VOMITING OR DIARRHEA, for any reason, or IF YOU TAKE CERTAIN MEDICINES, including some antibiotics or the herbal supplement St. John's Wort, your pills may not work as well.**  
• Use a back-up method (such as condoms, spermicides, or diaphragm) until you check with your doctor or healthcare provider.  
6. **IF YOU HAVE TROUBLE REMEMBERING TO TAKE THE PILL, talk to your doctor or 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 doctor or 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 it at about the same time every day.  
2. **LOOK AT YOUR PILL PACK. IT WILL HAVE 28 PILLS.** This **28-pill pack** has 21 "active" (light yellow, orange, and red) pills (with hormones) for Weeks 1, 2, 3 and 7 "inactive" (green) pills (without hormones) for Week 4.  
3. **ALSO FIND:**  
• where on the pack to start taking the pills,  
• in what order to take the pills (follow the arrows), and  
• the week numbers as shown in the picture below.  
4. **BE SURE YOU HAVE READY AT ALL TIMES:**  
• **ANOTHER KIND OF BIRTH CONTROL** (such as condoms, spermicides, or diaphragm) to use as a back-up in case you miss pills.  
• **AN EXTRA, FULL PILL PACK OF CYCLESSA® (desogestrel/ethinyl estradiol) Tablets.**

**WHEN TO START THE FIRST PACK OF PILLS**  
You have a choice of which day to start taking your first pack of pills. Decide with your doctor or healthcare provider which is the best day for you. Pick a time of day which will be easy to remember.  
**DAY 1 START:**  
1. Pick the day label strip that starts with the first day of your period (this is the day you start bleeding or spotting, even if it is almost midnight when the bleeding begins).  
2. Place this day label strip in the cycle tablet dispenser over the area that has the days of the week (starting with Sunday) imprinted in the plastic.  
3. Pick correct day label. Example Only: 

1. **BE SURE YOU HAVE READY AT ALL TIMES:**  
• **ANOTHER KIND OF BIRTH CONTROL** (such as condoms, spermicides, or diaphragm) to use as a back-up in case you miss pills.  
• **AN EXTRA, FULL PILL PACK OF CYCLESSA® (desogestrel/ethinyl estradiol) Tablets.**

**WHEN TO START THE FIRST PACK OF PILLS**  
You have a choice of which day to start taking your first pack of pills. Decide with your doctor or healthcare provider which is the best day for you. Pick a time of day which will be easy to remember.  
**DAY 1 START:**  
1. Pick the day label strip that starts with the first day of your period (this is the day you start bleeding or spotting, even if it is almost midnight when the bleeding begins).  
2. Place this day label strip in the cycle tablet dispenser over the area that has the days of the week (starting with Sunday) imprinted in the plastic.  
3. Pick correct day label. Example Only: 

Note: If the first day of your period is a Sunday, you can skip steps #1 and #2.  
3. Take the first "active" (light yellow) pill of the first pack during the first 24 hours of your period.  
4. 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 "active" (light yellow) pill of the first pack on the first 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 as a back-up method if you have sex anytime from the Sunday you start your first pack until the next Sunday (7 days). Condoms, spermicides, or a diaphragm are good back-up methods of birth control.

**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 OR SWITCH YOUR BRAND OF PILLS:**  
Start the next pack on the day after your last pill. Do not wait any days between packs.

**WHAT TO DO IF YOU MISS PILLS**  
If you **MISS 1 "active"** (light yellow, orange, or red) pill:  
1. Take it as soon as you remember. Take the next pill at your regular time. This means you may take 2 pills in 1 day.  
2. You do not need to use a back-up birth control method if you have sex.  
If you **MISS 2 "active"** (light yellow or orange) pills in a row in **WEEK 1 OR WEEK 2** of your pack:  
1. Take 2 pills on the day you remember and 2 pills the next day.  
2. Then take 1 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, spermicides, or diaphragm) as a back-up method for those 7 days.  
If you **MISS 2 "active"** (red) pills in a row in **WEEK 3:**  
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 may not have your period this month, but this is expected. However, if you miss your period 2 months in a row, call your doctor or healthcare provider because you might be pregnant.  
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, spermicides, or diaphragm) as a back-up method for those 7 days.

If you **MISS 3 OR MORE "active"** (light yellow, orange, or red) pills in a row (during the first 3 weeks):  
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 may not have your period this month, but this is expected. However, if you miss your period 2 months in a row, call your doctor or healthcare provider because you might be pregnant.  
3. You **COULD BECOME PREGNANT** if you have sex on the days when you missed pills or during the first **7 days** after restarting your pills. You **MUST** use another birth control method (such as condoms, spermicides, or diaphragm) as a back-up method the next time you have sex and for the first 7 days after you restart your pills.

**IF YOU FORGET ANY OF THE 7 "INACTIVE" (GREEN) PILLS IN WEEK 4:**  
1. THROW AWAY the pills you missed.  
2. Keep taking 1 pill each day until the pack is empty.  
3. You do not need to use a back-up method of birth control.  
**FINALLY, IF YOU ARE STILL NOT SURE WHAT TO DO ABOUT THE PILLS YOU HAVE MISSED:**  
1. Use a BACK-UP METHOD of birth control anytime you have sex.  
2. **KEEP TAKING ONE "ACTIVE" (LIGHT YELLOW, ORANGE, OR RED) PILL EACH DAY** until you can reach your doctor or healthcare provider.

**DETAILED PATIENT PACKAGE INSERT**  
**Cyclessa® (desogestrel/ethinyl estradiol) 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.**

**IF ONLY PLEASE NOTE:** This labeling is revised from time to time as important new medical information becomes available. Therefore, please review this labeling carefully.  
**DESCRIPTION**  
Cyclessa® (desogestrel/ethinyl estradiol) Tablets are a triphasic oral contraceptive product, containing a combination of a progestin and estrogen, the two kinds of female hormones. Each light yellow tablet contains 0.100 mg desogestrel and 0.025 mg ethinyl estradiol; each orange tablet contains 0.100 mg desogestrel and 0.025 mg ethinyl estradiol, and each red tablet contains 0.150 mg desogestrel and 0.025 mg ethinyl estradiol. Each green tablet contains inert ingredients.

**INTRODUCTION**  
Any woman who considers using oral contraceptives (the birth control pill or the patch) should understand the benefits and risks of using this form of birth control. This leaflet will give you much of the information you will need to make this decision 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 doctor or healthcare provider. You should discuss the information provided in this leaflet with him or her, both when you first start taking the pill and anytime you have questions. You should also follow your doctor's or healthcare provider's advice with regard to regular check-ups while you are on the pill.  
**EFFECTIVENESS OF ORAL CONTRACEPTIVES**  
Oral contraceptives or "birth control pills" or "the pill" are used to prevent pregnancy and are more effective than other non-surgical methods of birth control. When they are taken correctly, the chance of becoming pregnant is less than 1% (1 pregnancy per 100 women per year of use), when used perfectly, without missing any pills. Typical failure rates are actually 5% (5 pregnancies per 100 women per year of use). The chance of becoming pregnant increases with each missed pill during a menstrual cycle.  
In comparison, typical failure rates for other methods of birth control during the first year of use are as follows:  
No methods: 85%  
Spermicides alone: 26%  
Condom alone (male): 14%  
Condom alone (female): 21%  
Cervical Cap with spermicides: 20 to 40%  
Vaginal insertion: 20 to 40%  
Diaphragm with spermicides: 20%  
Withdrawal: 19%  
Condom alone (male): 14%  
IUD: less than 1 to 2%  
Implants: less than 1%  
Injectable progestogens: less than 1%  
Male sterilization: less than 1%  
Female sterilization: less than 1%

**WHO SHOULD NOT TAKE ORAL CONTRACEPTIVES**  
Cigarette smoking increases the risk of serious cardiovascular side effects 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 are strongly advised not to smoke.  
Some women should not use the pill. For example, you should not take the pill if you are pregnant or have a history of blood clots in the legs (thrombophlebitis), lungs (pulmonary embolism), or eyes.  
• A history of heart attack or stroke  
• A history of blood clots in the legs (thrombophlebitis), lungs (pulmonary embolism), or eyes  
• Chest pain (angina pectoris)  
• Severe high blood pressure  
• Diabetes with complications of the kidneys, eyes, nerves, or blood vessels  
• Headache with neurologic symptoms  
• Known or suspected breast cancer or cancer of the lining of the uterus, cervix, or vagina (now or in the past)  
• Unexplained vaginal bleeding (until a diagnosis is reached by your healthcare provider)  
• Yellowing of the whites of the eyes or of the skin (jaundice) during pregnancy or during previous use of hormonal birth control of any kind (the pill, patch, vaginal ring, injection, or implant)  
• Liver tumor (benign or cancerous)  
• Heart valve or heart rhythm disorders that may be associated with formation of blood clots  
• Need for a long period of bed rest following major surgery  
• Known or suspected pregnancy  
• Active liver disease with abnormal liver function tests  
• An allergy or hypersensitivity to any of the components of Cyclessa® (desogestrel/ethinyl estradiol) Tablets

Tell your doctor or healthcare provider if you have ever had any of the above conditions. Your doctor or healthcare provider will recommend whether you should use the pill or not.  
**OTHER CONSIDERATIONS BEFORE TAKING ORAL CONTRACEPTIVES**  
Tell your doctor or healthcare provider if you have:  
• Breast nodules, fibrocystic disease of the breast, an abnormal breast x-ray or mammogram  
• Diabetes  
• Elevated cholesterol or triglycerides  
• High blood pressure  
• Migraine or other headaches or epilepsy  
• Depression  
• Gallbladder, liver, heart, or kidney disease  
• Scanty or irregular menstrual periods  
Women with any of these conditions should be checked often by their doctor or healthcare provider if they choose to use oral contraceptives.  
Talk to your healthcare provider about using Cyclessa® if you:  
• Smoke  
• Recently had a baby  
• Recently had a miscarriage or abortion  
• Are breast-feeding  
• Are taking any other medications

**RISKS OF TAKING ORAL CONTRACEPTIVES**  
**1. Risk of developing blood clots**  
Blood clots and blockage of blood vessels are one of the most serious side effects of taking oral contraceptives and can cause death or serious disability. In particular, a clot in the leg can cause thrombophlebitis and a clot that travels to the lungs can cause a sudden blockage of a vessel carrying blood to the lungs. The risks of these side effects may be greater with desogestrel-containing oral contraceptives, such as Cyclessa® (desogestrel/ethinyl estradiol) Tablets, than with certain other low-dose pills. 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 or healthcare provider 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. It is advisable to wait for at least four 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 the section on Breast-feeding in GENERAL PRECAUTIONS).  
The risk of circulatory disease in oral contraceptive users may be higher in users of high-dose pills and may be greater with longer duration of oral contraceptive use. In addition, some of these increased risks may continue for a number of years after stopping oral contraceptives. The risk of venous thromboembolic disease associated with oral contraceptives does not increase with length of use and disappears after pill use is stopped. The risk of abnormal blood clotting increases with age in both users and non-users of oral contraceptives, but the increased risk from the oral contraceptive appears to be present at all ages. For women aged 20 to 44 it is estimated that about 1 in 2000 using oral contraceptives will be hospitalized each year because of abnormal clotting. Among non-users in the same age group, about 1 in 20,000 would be hospitalized each year. For oral contraceptive users in general, it has been estimated that in women between the ages of 15 and 34 the risk of death due to a circulatory disorder is about 1 in 12,000 per year, whereas for non-users the rate is about 1 in 50,000 per year. In the age group 35 to 44, the risk is estimated to be about 1 in 2500 per year for oral contraceptive users and about 1 in 10,000 per year for non-users.

**2. Heart attacks and strokes**  
Oral contraceptives may increase the tendency to develop strokes (blockage or rupture of blood vessels in the brain), angina pectoris (chest pain), 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.  
Women with migraine (especially migraine with aura) who take oral contraceptives also may be at a higher risk of stroke.  
**3. Gallbladder disease**  
Oral contraceptive users probably have a greater risk than non-users 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**  
Breast cancer has been diagnosed slightly more often in women who use the pill than in women of the same age who do not use the pill. This small increase in the number of breast cancer diagnoses gradually disappears during the 10 years after stopping use of the pill. It is not known whether the difference is caused by the pill. It may be that women taking the pill are examined more often, so that breast cancer is more likely to be detected. 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 usually 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.  
**6. Lipid metabolism and inflammation of the pancreas**  
In patients with inherited defects of lipid metabolism, there have been reports of significant elevations of plasma triglycerides during estrogen therapy. This has led to pancreatitis in some cases.

**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 various 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 NON-STERILE WOMEN, BY FERTILITY METHOD AND ACCORDING TO AGE**  

Method of control and outcome	15-19	20-24	25-29	30-34	35-39	40-44
No fertility control methods*	7.0	7.4	9.1	14.8	25.7	28.2
Oral contraceptives*	0.3	0.5	0.9	1.9	13.8	31.6
Non-sterile condom use**	2.2	3.4	6.6	13.5	51.1	117.2
Oral contraceptives**	0.8	0.8	1.0	1.0	1.4	1.4
Condom**	1.1	1.6	0.7	0.2	0.3	0.4
Diaphragm/spermicide**	1.9	1.2	1.2	1.3	2.2	2.8
Periodic abstinence**	2.5	1.6	1.6	1.7	2.9	3.6

\*Deaths are method related.  
\*\*Deaths are method related.

In the above table, the risk of death from any birth control method is less than the risk of child-birth, 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 the method of birth control). For women aged 40 and over, 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 times higher (17 per 100,000 women) than the estimated risk associated with pregnancy (26 per 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 in the Advisory Committee of the FDA discussed in the section on 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 or healthcare provider 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)  
• Stomach 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 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)

**WARNING SIGNALS**  
If any of these adverse effects occur while you are taking oral contraceptives, call your doctor or healthcare provider 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)  
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• Jaundice or a 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)

**WARNING SIGNALS**  
If any of these adverse effects occur while you are taking oral contraceptives, call your doctor or healthcare provider 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)  
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7. **IF YOU HAVE ANY QUESTIONS OR ARE UNSURE ABOUT THE INFORMATION IN THIS LEAFLET, call your doctor or 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 it at about the same time every day.  
2. **LOOK AT YOUR PILL PACK. IT WILL HAVE 28 PILLS.** This **28-pill pack** has 21 "active" (light yellow, orange, and red) pills (with hormones) for Weeks 1, 2, 3 and 7 "inactive" (green) pills (without hormones) for Week 4.  
3. **ALSO FIND:**  
• where on the pack to start taking the pills,  
• in what order to take the pills (follow the arrows), and  
• the week numbers as shown in the picture below.  
