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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 pill users is less

than 5% per year (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 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. 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 malignant 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 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 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), stoppage 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 health care 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 herbal 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 the lining of the uterus.

Be sure to discuss any medical condition you may have with your doctor or health care provider. Your doctor or health care 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 health care 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 health care 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®

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.** 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 health care 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 health care provider.
6. IF YOU HAVE TROUBLE REMEMBERING TO TAKE THE PILL, talk to your doctor or health care 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 health care 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:

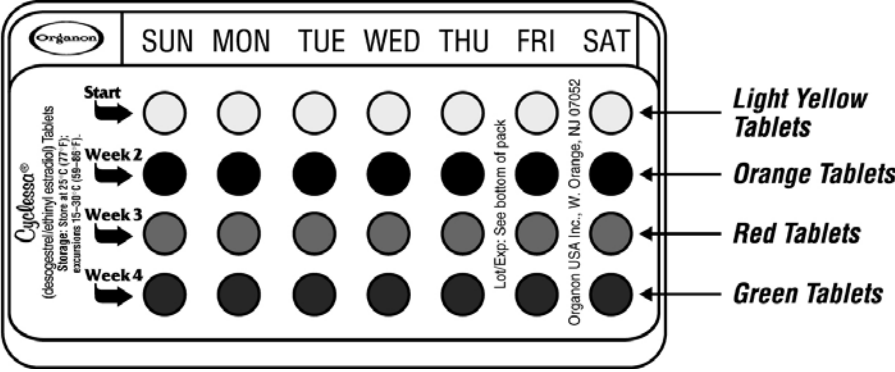
This **28-pill pack** has 21 “active” [light yellow, orange, and red] pills (with hormones) for Weeks 1, 2, 3 and 7 “inactive” green pills (without hormones) for Week 4.

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.

28 Pill Pack

**Example
Only:**



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®.**

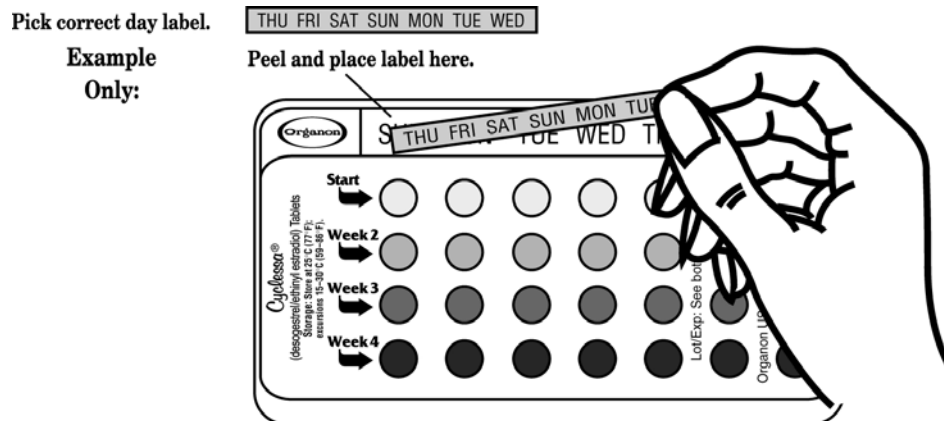
WHEN TO START THE FIRST PACK OF PILLS

You have a choice of which day to start taking your first pack of pills. Decide with your doctor or health care 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.



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 health care 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 health care 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 health care 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.

R_x 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 0.125 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 pill) 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 health care provider. 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 doctor's or health care 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%

Periodic abstinence: 25%

Withdrawal: 19%

Cervical Cap with spermicides: 20 to 40%

Vaginal sponge: 20 to 40%

Diaphragm with spermicides: 20%

Condom alone (female): 21%

Condom alone (male): 14%

IUD: less than 1 to 2%

Implants: less than 1%

Injectable progestogen: 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 think you may be pregnant. You should also not use the pill if you have any of the following conditions:

- A history of heart attack or stroke
- A history of blood clots in the legs (thrombophlebitis), lungs (pulmonary embolism), or eyes
- A history of blood clots in the deep veins of your legs
- Chest pain (angina pectoris)
- Severe high blood pressure
- Diabetes with complications of the kidneys, eyes, nerves or blood vessels
- Headache with neurological 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 health care 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®.

Tell your doctor or health care provider if you have ever had any of the above conditions. Your doctor or health care provider can recommend another method of birth control.

OTHER CONSIDERATIONS BEFORE TAKING ORAL CONTRACEPTIVES

Tell your doctor or health care 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 health care 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 breastfeeding
- 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 health care 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 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. There is insufficient evidence to rule out the possibility that pills may cause such cancers.

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 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	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 non-smoker**	0.3	0.5	0.9	1.9	13.8	31.6
Oral contraceptives smoker**	2.2	3.4	6.6	13.5	51.1	117.2
IUD**	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 birth related

** Deaths are method related

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 is always lower than that associated with pregnancy for any age group, although over the age of 40, 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 per 100,000 women) than the estimated risk associated with pregnancy (28 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 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 or health care 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 health care 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 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

In addition to the risks and more serious side effects discussed above (see **RISKS OF TAKING ORAL CONTRACEPTIVES, ESTIMATED RISK OF DEATH FROM A BIRTH CONTROL METHOD OR PREGNANCY** and **WARNING SIGNALS** sections), the following may also occur:

1. Irregular 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 health care 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 health care provider.

3. Fluid retention or raised blood pressure

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 health care 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 and 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 health care 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 doctor or health care provider before doing so. 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 doctor or health care provider immediately to determine whether you are pregnant.

Stop taking Cyclessa if you are pregnant.

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 or any other drugs should not be used during pregnancy unless clearly necessary and prescribed by your doctor or health care provider. You should check with your doctor or health care provider about risks to your unborn child of any medication taken during pregnancy.

2. While breast feeding

If you are breast feeding, consult your doctor or health care provider 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 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 or health care provider 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), phenytoin (Dilantin[®] is one brand of this drug), phenylbutazone (Butazolidin[®] is one brand), herbal products containing St. John's Wort (*hypericum perforatum*), and possibly certain antibiotics. You may need to use additional contraception when you take drugs which can make oral contraceptives less effective. Be sure to tell your health care provider if you are taking or start taking any medications while taking birth control pills.

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.

HOW TO TAKE CYCLESSA[®]

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.** 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 health care 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 health care provider.
6. IF YOU HAVE TROUBLE REMEMBERING TO TAKE THE PILL, talk to your doctor or health care 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 health care 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:

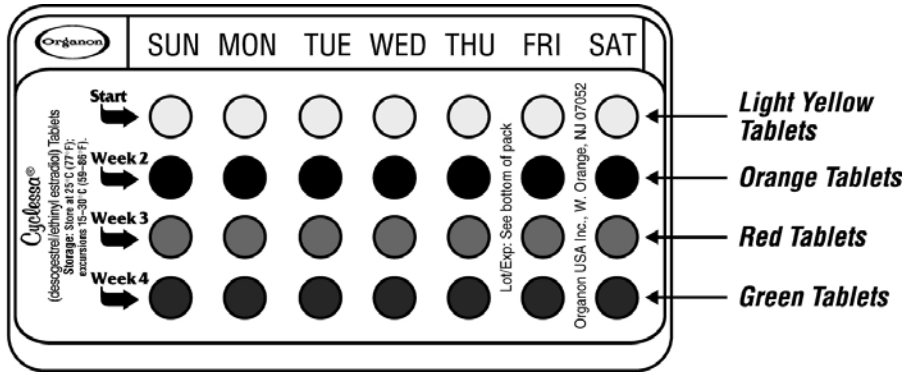
This **28-pill pack** has 21 "active" [light yellow, orange, and red] pills (with hormones) for Weeks 1, 2, 3 and 7 "inactive" [green] pills (without hormones) for Week 4.

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.

28 Pill Pack

Example Only:



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®.

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 health care provider which is the best day for you. Pick a time of day which will be easy to remember.

DAY 1 START:

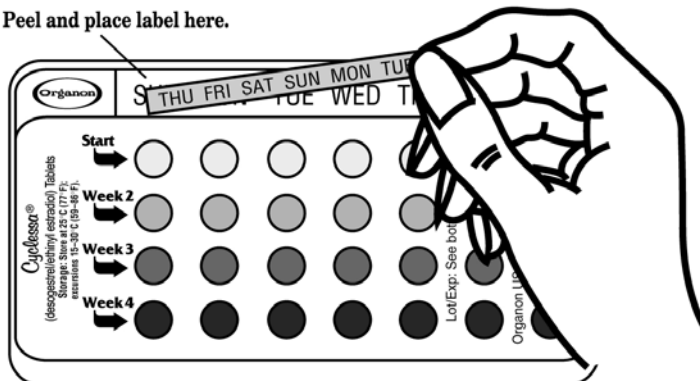
1. Pick the day label strip that starts with the first day of your period (this is the day you start bleeding or spotting, even if it is almost midnight when the bleeding begins).
2. Place this day label strip in the cycle tablet dispenser over the area that has the days of the week (starting with Sunday) imprinted in the plastic.

Pick correct day label.

Example Only:

THU FRI SAT SUN MON TUE WED

Peel and place label here.



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 health care 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 health care 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 health care provider.

ADDITIONAL INFORMATION

1. PREGNANCY DUE TO PILL FAILURE

The incidence of pill failure resulting in pregnancy is approximately one percent (i.e., one pregnancy per 100 women per year of use) if taken every day as directed, but more typical failure rates are about 5% (5 pregnancies per 100 women per year of use). If failure does occur, the risk to the fetus is minimal.

2. 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.

3. OVERDOSAGE

Serious ill effects have not been reported following ingestion of large doses of oral contraceptives by young children. Overdosage may cause nausea and withdrawal bleeding in females. In case of overdosage, contact your doctor, health care provider or pharmacist.

4. OTHER INFORMATION

Your doctor or health care provider will take a medical and family history and may examine you before prescribing an oral contraceptive. The physical examination may be delayed to another time if you request it and your doctor or the health care provider believes that it is a good medical practice to postpone it. You should be reexamined at least once a year. Be sure to inform your doctor or health care 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 doctor or health care 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 combination 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.
- ectopic (tubal) pregnancy may occur less frequently.
- non-cancerous 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, health care provider, or pharmacist.

They have a more technical leaflet called the Prescribing Information which you may wish to read.



Manufactured for Organon USA Inc., Roseland, NJ 07068

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