

## PATIENT PACKAGE INSERT BRIEF SUMMARY

### **CYCLESSA<sup>®</sup> Tablets (desogestrel and ethinyl estradiol tablets USP)**

#### **28 Day Regimen**

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

#### **Rx only**

CYCLESSA<sup>®</sup> Tablets (desogestrel and ethinyl estradiol tablets USP) is a triphasic oral contraceptive containing 7 round light yellow tablets, 7 round orange tablets, 7 round red tablets, and 7 round green tablets in a blister card. 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.

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 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 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 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®**

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#### **IMPORTANT POINTS TO REMEMBER**

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##### **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.

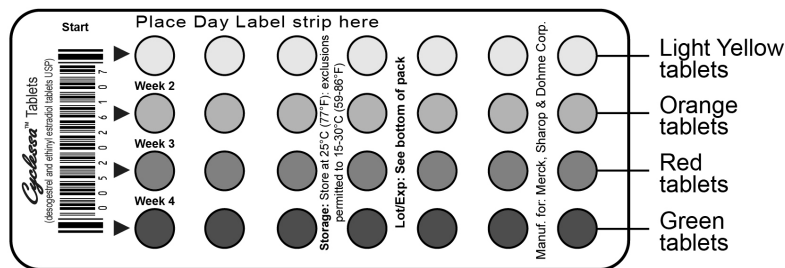
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## BEFORE YOU START TAKING YOUR PILLS

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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<sup>®</sup> Tablets (desogestrel and ethinyl estradiol tablets USP).

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## WHEN TO START THE FIRST PACK OF PILLS

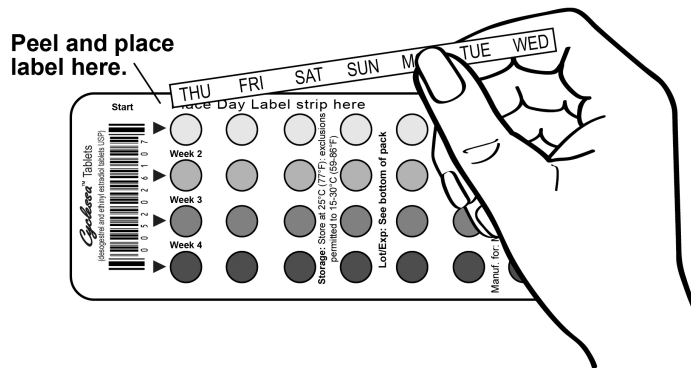
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You have a choice of which day to start taking your first pack of pills. Decide with your doctor or healthcare provider which is the best day for you. Pick a time of day which will be easy to remember.

### 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 on the blister card above the first row of tablets.

Pick correct day label. THU FRI SAT SUN MON TUE WED



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.

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### WHAT TO DO DURING THE MONTH

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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.

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### WHAT TO DO IF YOU MISS PILLS

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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.

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**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.

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**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.

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For patent information: [www.merck.com/product/patent/home.html](http://www.merck.com/product/patent/home.html)

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