

Duramed Pharmaceuticals, Inc.**SEASONALE[®] (levonorgestrel / ethinyl estradiol tablets) 0.15 mg / 0.03 mg****DETAILED PATIENT LABELING**

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

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. Although oral contraceptives have important advantages over other methods of contraception, they have certain risks that no other method has, and some of these risks may continue after you have stopped using the oral contraceptive. 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 Seasonale[®] 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 provider. You should discuss the information provided in this leaflet with your healthcare provider, both when you first start taking Seasonale[®] and during your revisits. You should also follow your healthcare provider's advice with regard to regular check-ups while you are on Seasonale[®].

EFFECTIVENESS OF ORAL CONTRACEPTIVES

Oral contraceptives or “the birth control pill” or “the pill” are used to prevent pregnancy and are more effective than most other nonsurgical methods of birth control. The chance of becoming pregnant is approximately 1.0% per year (1 pregnancy per 100 women per year of use) when the pills are used correctly, and no pills are missed. Typical failure rates are approximately 5.0% per year when women who miss pills are included. The chance of becoming pregnant increases with each missed pill during the 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%
Vaginal sponge: 20 to 40%
Cervical cap: 20 to 40%
Spermicides alone: 26%
Periodic abstinence: 25%
Condom (female): 21%
Diaphragm with spermicides: 20%
Withdrawal: 19%
Condom (male): 14%

Female sterilization: 0.5%
IUD: 0.1 to 2.0%
Injectable progestogen: 0.3%
Male sterilization: 0.15%
Norplant system: 0.05%

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 the amount of smoking (15 or more cigarettes per day has been associated with a significantly increased risk) and is quite marked in women over 35 years of age. Women who use oral contraceptives should not smoke.

Some women should not use the pill. You should 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)
- Known or suspected breast cancer or cancer of the lining of the uterus, cervix, vagina, or certain hormonally-sensitive cancers
- 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 the pill
- Liver tumor (benign or cancerous)
- Known or suspected pregnancy
- Heart valve or heart rhythm disorders that may be associated with formation of blood clots
- Diabetes affecting your circulation
- Uncontrolled high blood pressure
- Active liver disease with abnormal liver function tests
- Allergy or hypersensitivity to any of the components of Seasonale[®]
- A need for surgery with prolonged bedrest

Tell your healthcare provider if you have any of the above conditions. Your healthcare provider can recommend a safer method of birth control.

OTHER CONSIDERATIONS BEFORE TAKING ORAL CONTRACEPTIVES

Tell your healthcare provider if you or any family member has ever had:

- 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
- 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 healthcare provider if you smoke or are on any medications.

RISKS OF TAKING ORAL CONTRACEPTIVES

If you use Seasonale® you will receive more exposure to hormones on a yearly basis than if you used a conventional 28-day cycle oral contraceptives containing a similar amount of estrogen and progestin (an additional 9 weeks exposure per year). While this added exposure may pose an additional risk of thrombotic and thromboembolic disease, studies to date with Seasonale have not suggested an increased risk of these disorders.

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 cause death or serious disability. In particular, a clot in the legs can cause thrombophlebitis and a clot that travels to the lungs can cause a sudden blocking of the vessel carrying blood to the lungs. Rarely, clots occur in the blood vessels of the eye and may cause blindness, double vision, or impaired vision.

If you take oral contraceptives and need elective surgery, need to stay in bed for a prolonged illness, or have recently delivered a baby, you may be at risk of developing blood clots. You should consult your 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 breastfeeding. If you are breastfeeding, you should wait until you have weaned your child before using the pill (See also the section on **Breastfeeding** in “**GENERAL PRECAUTIONS**”).

The risk of circulatory disease in oral contraceptive users may be higher in users of high-dose pills (containing 50 micrograms or higher of ethinyl estradiol) 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 abnormal blood clotting increases with age in both users and nonusers 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 2,000 using oral contraceptives will be hospitalized each year because of abnormal clotting. Among nonusers 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 nonusers 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 2,500 per year for oral contraceptive users and about 1 in 10,000 per year for nonusers.

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.

Women with migraine (especially migraine with aura) who take oral contraceptives also may be at higher risk of stroke.

3. Gallbladder Disease

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

4. Liver Tumors

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

5. Cancer of the Breast and Reproductive Organs

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 or precancerous lesions 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 the pill may cause such cancers.

6. Lipid Metabolism and Inflammation of the Pancreas

In patients with inherited defects of the 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 AND ACCORDING TO AGE

Method of control and outcome	AGE					
	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 to 26 deaths per 100,000 women, depending on age). Among pill users who do not smoke, the risk of death was always lower than that associated with pregnancy for any age group, 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 (117/100,000 women) than the estimated risk associated with pregnancy (28/100,000 women) in that age group.

The suggestion that women over 40 who don't smoke should not take oral contraceptives is based on information from older high-dose pills. An Advisory Committee of the FDA discussed this issue in 1989 and recommended that the benefits of oral contraceptive use by healthy, nonsmoking women over 40 years of age may outweigh the possible risks. Older women, as all women who take oral contraceptives, should take an oral contraceptive that contains the least amount of estrogen and progestin that is compatible with the individual patient needs.

WARNING SIGNALS

If any of these adverse effects occur while you are taking oral contraceptives, call your 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).
- 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 (bleeding or spotting between your expected period) is likely to occur while you are taking Seasonale[®]. 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 91-day cycles of Seasonale[®] use, tends to decrease during later cycles, but may also occur after you have been taking Seasonale[®] for some time. Such bleeding usually does not indicate any serious problems. **It is important to continue taking your pills on schedule even if you are having irregular bleeding.** If the bleeding lasts for more than 7 consecutive days, talk to your healthcare provider.

When you take Seasonale[®], you need to consider the convenience of fewer expected menstrual periods (4 per year instead of 13) and the inconvenience of more irregular vaginal bleeding or spotting. In a clinical trial comparing Seasonale[®] (91-day cycles) to a conventional equivalent dosage 28-day cycle oral contraceptive, more women using Seasonale[®] discontinued treatment because of bleeding problems (7.7% of the Seasonale[®] users compared to 1.8% of the 28-day cycle users).

The following Table shows the percentages of women with 7 or more and 20 or more days of intermenstrual bleeding and/or spotting in the Seasonale[®] and the 28-day cycle treatment groups.

Percentages (%) of Women with Intermenstrual Bleeding and/or Spotting

Number of days of intermenstrual bleeding and/or spotting	Percentage of subjects with intermenstrual bleeding or spotting*	
	Seasonale [®]	28-day cycle pill
	Cycle 1	Cycle 4
7 or more days	65%	42%
20 or more days	35%	15%
	Cycles 1-4	Cycles 10-13
7 or more	38%	39%
20 or more days	6%	4%

* Based on spotting and/or bleeding on days 1-84 of a 91 day cycle in the Seasonale[®] subjects and days 1-21 of a 28 day cycle over 4 cycles in the 28-day dosing regimen.

Total days of bleeding and/or spotting (withdrawal plus intermenstrual) were similar over one year of treatment for Seasonale[®] subjects and subjects on the 28-day cycle regimen.

2. **Contact lenses**

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

3. **Fluid retention**

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

4. **Melasma**

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

5. Other side effects

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

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

GENERAL PRECAUTIONS

1. Missed Periods and Use of Oral Contraceptives Before or During Early Pregnancy

If you miss any periods (no bleeding on the days that you take white pills), you must consider the possibility that you may be pregnant. Notify your healthcare provider that you are taking Seasonale[®] and have missed your period. Also notify your healthcare provider if you have symptoms of pregnancy such as morning sickness or unusual breast tenderness. Because you are taking Seasonale[®], it is very important that your healthcare provider evaluates you to determine if you are pregnant. Stop taking Seasonale[®] 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 should not be used during pregnancy. You should check with your healthcare provider about risks to your unborn child of any medication taken during pregnancy.

2. While Breastfeeding

If you are breastfeeding, consult your healthcare 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 breastfeeding. You should use another method of contraception since breastfeeding 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 healthcare 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), carbamazepine (Tegretol is one brand of this drug), and phenytoin (Dilantin[®] is one brand of this drug), primidone (Mysoline[®]), topiramate

(Topamax[®]), phenylbutazone (Butazolidin[®] is one brand), some drugs used for HIV such as ritonavir (Norvir[®]), modafinil (Provigil[®]) and possibly certain antibiotics (such as ampicillin and other penicillins, and tetracyclines). Pregnancies and breakthrough bleeding have been reported by users of combined hormonal contraceptives who also used some form of the herbal supplement St. John's Wort. You may need to use a non-hormonal method of contraception during any cycle in which you take drugs that can make oral contraceptives less effective. Be sure to tell your healthcare provider if you are taking or start taking any other medications, including nonprescription products or herbal products while taking birth control pills.

You may be at higher risk of a specific type of liver dysfunction if you take troleandomycin and oral contraceptives at the same time.

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.

What You Should Know About Your Menstrual Cycle When Taking Seasonale[®]

When you take Seasonale[®], which has a 91-day treatment cycle, you should expect to have 4 menstrual periods per year (bleeding when you are taking the 7 white pills). However, you should expect to have more bleeding or spotting between your menstrual periods than if you were taking an oral contraceptive with a 28-day treatment cycle. During the first Seasonale[®] treatment cycle, about 1 in 3 women may have 20 or more days of unplanned bleeding or spotting (bleeding when you are taking pink pills). This bleeding or spotting tends to decrease during later cycles. Do not stop Seasonale[®] because of the bleeding. If the spotting continues for more than 7 consecutive days or if the bleeding is heavy, call your healthcare provider.

HOW TO TAKE SEASONALE[®]

IMPORTANT POINTS TO REMEMBER *BEFORE* YOU START TAKING SEASONALE[®]

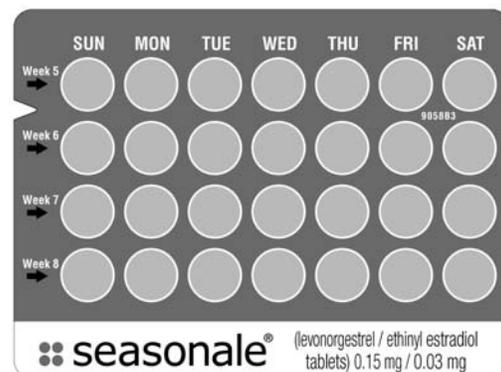
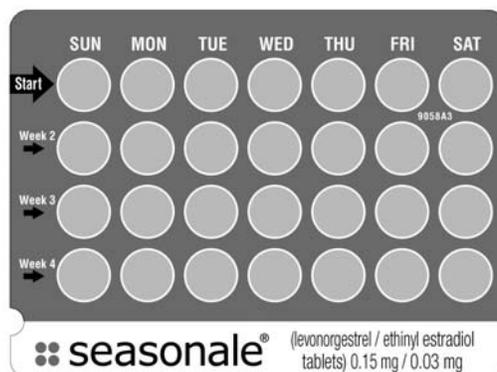
1. BE SURE TO READ THESE DIRECTIONS:
 - Before you start taking your pills.
 - Anytime you are not sure what to do.
2. THE RIGHT WAY TO TAKE SEASONALE[®] IS TO TAKE ONE PILL EVERY DAY AT THE SAME TIME.

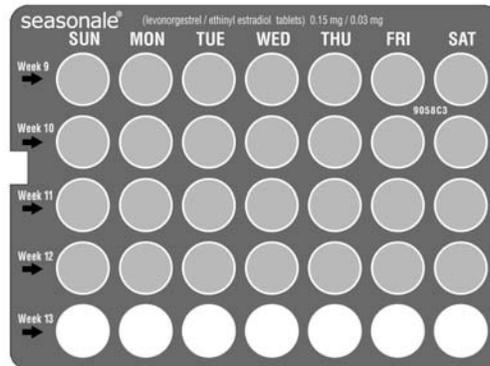
If you miss pills you could get pregnant. This includes starting the pack late. The more pills you miss, the more likely you are to get pregnant.
3. MANY WOMEN MAY FEEL SICK TO THEIR STOMACH DURING THE FIRST FEW WEEKS OF TAKING PILLS.

- If you 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 healthcare provider.
- MANY WOMEN HAVE SPOTTING OR LIGHT BLEEDING DURING THE FIRST FEW MONTHS OF TAKING SEASONALE[®]. **Do not stop taking your pills even if you are having irregular bleeding.** If the bleeding lasts for more than a few days, talk to your healthcare provider.
 - 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.
 - IF YOU HAVE VOMITING OR DIARRHEA, or IF YOU TAKE SOME MEDICINES, including some antibiotics and the herbal supplement St. John's Wort, seasonale may not work as well. Use a back-up method (such as condoms or spermicides) until you check with your healthcare provider.
 - IF YOU HAVE TROUBLE REMEMBERING TO TAKE SEASONALE[®], talk to your healthcare provider about how to make pill-taking easier or about using another method of birth control.
 - IF YOU HAVE ANY QUESTIONS OR ARE UNSURE ABOUT THE INFORMATION IN THIS LEAFLET, call your healthcare provider.

BEFORE YOU START TAKING SEASONALE[®]

- DECIDE WHAT TIME OF DAY YOU WANT TO TAKE YOUR PILL. It is important to take it at about the same time every day.
- LOOK AT YOUR EXTENDED-CYCLE TABLET. Your Tablet Dispenser consists of 3 trays with cards that hold 91 individually sealed pills (a 13-week or 91-day cycle). The 91 pills consist of 84 pink pills (active pills with hormones) and 7 white pills (inactive pills without hormone). Trays 1 and 2 each contain 28 pink pills (4 rows of 7 pills). Tray 3 contains 35 pills consisting of 28 pink pills (4 rows of 7 pills) and 7 white pills (1 row of 7 pills).





3. ALSO FIND:

- Where on the first tray in the pack to start taking pills (upper left corner at the start arrow) and
 - In what order to take the pills (follow the weeks and arrow).
4. BE SURE YOU HAVE READY AT ALL TIMES ANOTHER KIND OF BIRTH CONTROL (such as condoms or spermicides), to use as a back-up in case you miss pills.

WHEN TO START SEASONALE®

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

HOW TO TAKE SEASONALE®

1. **Take one pill at the same time every day until you have taken the last pill in the tablet dispenser.**
Do not skip pills even if you are spotting or bleeding 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 TABLET DISPENSER.**
 After taking the last white pill, start taking the first pink pill from a new Extended-Cycle Tablet Dispenser **the very next day** regardless of when your period started. This should be on a Sunday.
3. **If you miss your period when you are taking the white pills, call your healthcare provider because you may be pregnant.**

WHAT TO DO IF YOU MISS PILLS

If you **MISS 1** pink “active” 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** pink “active” pills in a row:

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 or spermicide) as a back-up on the 7 days after you restart your pills.

If you **MISS 3 OR MORE** pink “active” pills in a row:

1. Do not remove the missed pills from the pack as they will not be taken. Keep taking 1 pill every day as indicated on the pack until you have completed all of the remaining pills in the pack. For example: If you resume taking the pill on Thursday, take the pill under “Thursday” and do not take the missed pills. You may experience bleeding during the week following the missed pills.
2. You **COULD BECOME PREGNANT** if you have sex during the days of missed pills or during the first 7 days after restarting your pills.
3. You **must** use a non-hormonal birth control method (such as condoms or spermicide) as a back-up when you miss pills and for the first 7 days after you restart your pills. **If you miss your period when you are taking the white pills, call your healthcare provider because you may be pregnant.**

If you **MISS ANY** of the 7 white inactive pills.

- a. Throw away the missed pills.
- b. Keep taking the scheduled pills until the pack is finished.
- c. You do not need a back-up method of birth control.

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

1. Use a **BACK-UP METHOD** anytime you have sex.
2. **KEEP TAKING ONE PILL EACH DAY** until you contact your healthcare provider.

PREGNANCY DUE TO PILL FAILURE

If taken every day as directed, the incidence of pill failure resulting in pregnancy is approximately 1 % (ie, one pregnancy per 100 women per year), but more typical failure rates are about 5%. If failure does occur, the risk to the fetus is minimal.

PREGNANCY AFTER STOPPING THE PILL

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

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

OVERDOSAGE

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

OTHER INFORMATION

Your healthcare provider will take a medical and family history before prescribing oral contraceptives and will examine you. The physical examination may be delayed to another time if you request it and the healthcare provider believes that it is appropriate to postpone it. You should be reexamined at least once a year. Be sure to inform your healthcare provider if there is a family history of any of the conditions listed previously in this leaflet. Be sure to keep all appointments with your healthcare provider, because this is a time to determine if there are early signs of side effects of oral contraceptive use. Do not use the drug for any condition other than the one for which it was prescribed. This drug has been prescribed specifically for you; do not give it to others who may want birth control pills.

NONCONTRACEPTIVE HEALTH BENEFITS

The following noncontraceptive health benefits related to the use of oral contraceptives are supported by epidemiological studies which largely utilized oral contraceptive formulations containing doses exceeding 0.035 mg of ethinyl estradiol or 0.05 mg of mestranol.

Effects on menses:

- May decrease blood loss and may decrease incidence of iron-deficiency anemia
- May decrease incidence of dysmenorrhea

Effects related to inhibition of ovulation:

- May decrease incidence of functional ovarian cysts
- May decrease incidence of ectopic pregnancies

Effects from long-term use:

- May decrease incidence of fibroadenomas and fibrocystic disease of the breast
- May decrease incidence of acute pelvic inflammatory disease
- May decrease incidence of endometrial cancer
- May decrease incidence of ovarian cancer

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

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