

Patients should be counseled that this product does not protect against HIV infection (AIDS) and other sexually transmitted diseases.

COMBINATION ORAL CONTRACEPTIVES

Each of the following products is a combination oral contraceptive containing the progestational compound norethindrone and the estrogenic compound ethinyl estradiol.

ORTHO-NOVUM 7/7/7 Tablets: Each white tablet contains 0.5 mg of norethindrone and 0.035 mg of ethinyl estradiol.

ORTHO-NOVUM 1/25 Tablets: Each peach tablet contains 1 mg of norethindrone and 0.035 mg of ethinyl estradiol.

MODICON Tablets: Each white tablet contains 0.5 mg of norethindrone and 0.035 mg of ethinyl estradiol.

The chemical name for norethindrone is 17-Hydroxy-19-nor-17alpha-pregna-4-en-20-yn-3-one, for ethinyl estradiol is 19-Nor-17alpha-pregna-1,3,5(10)-trien-20-yn-3,17-diol.



CLINICAL PHARMACOLOGY

Combination oral contraceptives act by suppression of gonadotropins. Although the primary action is on the ovary, other effects include changes in the cervical mucus which increase the difficulty of sperm entry into the uterus and the endometrium (which reduce the likelihood of implantation).

INDICATIONS AND USAGE

ORTHO-NOVUM 7/7/7, ORTHO-NOVUM 1/25, and MODICON Tablets are indicated for the prevention of pregnancy in women who elect to use this product as a method of contraception.

Oral contraceptives are highly effective. Table 1 lists the typical accidental pregnancy rate for each combination oral contraceptive when used as directed.

Table 1: Percentage of Women Experiencing an Unintended Pregnancy. Columns: Method, Typical Use*, Perfect Use*. Rows: Chance, Condom, Progestin Only, etc.

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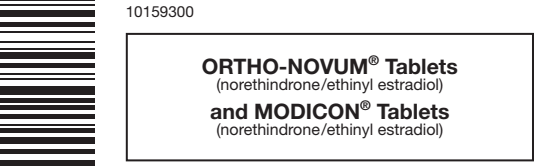
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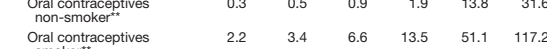
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ADVERSE REACTIONS

- An increased risk of the following serious adverse reactions has been associated with the use of oral contraceptives (See WARNINGS Section).
• Thrombophlebitis and venous thrombosis with or without embolism
• Arterial thrombosis with or without embolism
• Pulmonary embolism
• Myocardial infarction
• Cerebral thrombosis
• Hypertension
• Gallbladder disease
• Hepatic adenomas or benign liver tumors

There is evidence of an association between the following conditions and the use of oral contraceptives:
• Migraine
• Mesenteric thrombosis
• Retinal thrombosis

The following adverse reactions have been reported in patients receiving oral contraceptives on a long-term or drug-tolerance basis:
• Nausea
• Vomiting
• Headaches
• Breakthrough bleeding (such as abdominal cramps and bloating)
• Spotting
• Change in menstrual flow
• Amenorrhea
• Temporary infertility after discontinuation of treatment

Other adverse reactions which may occur include:
• Melasma which may persist
• Breast changes: tenderness, enlargement, secretion
• Change in weight (increase or decrease)
• Change in cervical erosion and secretion
• Diminution in lactation when given immediately postpartum
• Cholestatic jaundice
• Migraine
• Contact reaction, including rash, urticaria, angioedema
• Mental depression
• Reduced tolerance to carbohydrates

Concurrent use of the following drugs may increase the risk of oral contraceptives and may affect their effectiveness:
• Anticoagulants
• Anticonvulsants
• Barbiturates
• Corticosteroids
• Cytotoxic drugs
• Enzyme-inducing drugs
• Rifampin
• St. John's Wort

The following adverse reactions have been reported in users of oral contraceptives and a causal association has not been confirmed or refuted:
• Pre-menstrual syndrome
• Cataracts
• Decreased appetite
• Cystitis-like syndrome
• Headache
• Change in contact lens fitting
• Dizziness
• Hirsutism
• Rash
• Erythema multiforme
• Hemorrhagic colitis
• Hemorrhagic telangiectasia
• Vaginitis
• Impaired renal function
• Hemolytic uremic syndrome
• Changes in libido
• Colitis
• Bull's-Eye Rash Syndrome

OVERDOSAGE

Serious ill effects have not been reported following acute ingestion of large doses of oral contraceptives by young children. Overdose may cause nausea, and withdrawal bleeding may occur in females.

NON-CONTRACEPTIVE HEALTH BENEFITS

Oral contraceptives are widely used to treat a variety of conditions. The use of combination oral contraceptives are supported by epidemiological studies which largely utilized oral contraceptive formulations containing estrogen doses exceeding 0.035 mg of ethinyl estradiol or 0.5 mg of norethindrone.

Effects on menses:
• Increased menstrual cycle regularity
• Decreased blood loss and decreased incidence of iron deficiency anemia
• Decreased incidence of endometrial cancer
• Decreased incidence of functional ovarian cysts
• Decreased incidence of ectopic pregnancies
• Decreased incidence of fibroadenomas and fibrocystic disease of the breast
• Decreased incidence of acute pelvic inflammatory disease
• Decreased incidence of endometrial cancer
• Decreased incidence of ovarian cancer

DOSE AND ADMINISTRATION

To achieve maximum contraceptive effectiveness, ORTHO-NOVUM Tablets and MODICON Tablets must be taken exactly as directed and at intervals not exceeding 24 hours.

When taking ORTHO-NOVUM 7/7/7, ORTHO-NOVUM 1/25, and MODICON, the first active tablet should be taken on the first Sunday after menstruation begins. If period begins on Sunday, the first active tablet should be taken on the first Sunday after menstruation begins.

If the patient misses one (1) "active" tablet in Weeks 1, 2, or 3, the tablet should be taken as soon as remembered. If two (2) tablets are missed in Week 1 or Week 2, the patient should take two (2) tablets the day she remembers and two (2) tablets the next day, and then continue taking one (1) tablet a day until she finishes the pack. The patient should not use control pills or take control pills as condoms or spermicide if she has sex in the seven (7) days after missing pills. If the patient misses two (2) "active" tablets in the third week or misses three (3) or more "active" tablets in the fourth week, the patient should take one (1) tablet the day she remembers and two (2) tablets the next day. The patient should be instructed to use a back-up method of birth control for the next 7 days after the last active tablet is taken.

Complete instructions to facilitate patient counseling on proper pill usage may be found in the Detailed Patient Labeling ("How to Take the Pill" section).

Day 1 Start

The dosage of ORTHO-NOVUM 7/7/7, ORTHO-NOVUM 1/25, and MODICON, for the initial cycle is as follows: There is one "active" tablet administered daily from the first through the 21st day of the menstrual cycle, counting the first day of menstrual flow as "Day 1," followed by one "reminder" tablet daily for 7 days. Tablets are taken without interruption for 28 days. If no tablets have been taken, a new course is started the next day.

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Additional instructions:
• Breakthrough bleeding, spotting, and amenorrhea are frequent reasons for patients discontinuing oral contraceptives. In breakthrough bleeding, as in all cases of irregular bleeding from the vagina, nonfunctional causes should be borne in mind. In undiagnosed persistent or recurring abnormal vaginal bleeding, appropriate medical investigation should be conducted. If the patient has had a hysterectomy, appropriate medical investigation should be conducted. If the patient has had a hysterectomy, appropriate medical investigation should be conducted. If the patient has had a hysterectomy, appropriate medical investigation should be conducted.

HOW SUPPLIED
ORTHO-NOVUM 7/7/7 Tablets are available in a DIALPAK Tablet Dispenser (NDC 0062-1781-15) containing 28 tablets, as follows: 7 white, round, flat-faced beveled edge tablets imprinted "ORTHO 135" on both sides (0.5 mg norethindrone and 0.035 mg ethinyl estradiol), 7 light peach, round, flat-faced, beveled edged tablets imprinted "1/25" on both sides (1 mg norethindrone and 0.035 mg ethinyl estradiol), 7 peach, round, flat-faced, beveled edged tablets imprinted with "Ortho 135" on both sides (1 mg norethindrone and 0.035 mg ethinyl estradiol) and 7 green, round, flat-faced, beveled edged tablets imprinted "Ortho" on both sides containing inert ingredients.

ORTHO-NOVUM 1/25 Tablets are available in a VERIDATE Tablet Dispenser (unfilled) and VERIDATE Refills (NDC 0062-1781-20).
ORTHO-NOVUM 7/7/7 Tablets are available in a DIALPAK Tablet Dispenser (NDC 0062-1781-15) containing 28 tablets, as follows: 21 peach, round, flat-faced, beveled edged tablets imprinted "Ortho 135" on both sides (1 mg norethindrone and 0.035 mg ethinyl estradiol), 7 green, round, flat-faced, beveled edged tablets imprinted "Ortho" on both sides containing inert ingredients.

MODICON Tablets are available in a DIALPAK Tablet Dispenser (NDC 0062-1714-15) containing 28 tablets, as follows: 7 white, round, flat-faced, beveled edge tablets imprinted "MODICON 135" on both sides (0.5 mg norethindrone and 0.035 mg ethinyl estradiol), 7 light peach, round, flat-faced, beveled edged tablets imprinted "1/25" on both sides (1 mg norethindrone and 0.035 mg ethinyl estradiol), 7 peach, round, flat-faced, beveled edged tablets imprinted with "Ortho 135" on both sides (1 mg norethindrone and 0.035 mg ethinyl estradiol) and 7 green, round, flat-faced, beveled edged tablets imprinted "Ortho" on both sides containing inert ingredients.

MODICON is available for clinical use in a VERIDATE Tablet Dispenser (unfilled) and VERIDATE Refills (NDC 0062-1714-20).
Store at 25°C (77°F), excursions permitted to 15°-30°C (59°-86°F).

REFERENCES

1. Trussell J. Contraceptive efficacy. In Hatcher RA, Trussell J, Stewart F, Cates W, Stewart GK, Kowal D, Guest F. Contraceptive Technology: Seventeenth Revised Edition. New York: Raven Press, 1988; 103-114.
2. Trussell J, Coombs RW, Cates W, Stewart GK, Kowal D, Guest F. Contraceptive Technology: (Pt. 1). N Engl J Med 1981; 305:612-618.
3. Stadel BV. Oral contraceptives and cardiovascular disease. (Pt. 2). N Engl J Med 1981; 305:672-677.
4. Adams SA, Corcoran M, Bostrom M, et al. Oral contraceptives - time to change the message. JAMA 1989; 261:2294-2296.
5. Adams SA, Corcoran M, Bostrom M, et al. Oral contraceptives - time to change the message. JAMA 1989; 261:2294-2296.
6. Adams SA, Corcoran M, Bostrom M, et al. Oral contraceptives - time to change the message. JAMA 1989; 261:2294-2296.
7. Adams SA, Corcoran M, Bostrom M, et al. Oral contraceptives - time to change the message. JAMA 1989; 261:2294-2296.
8. Adams SA, Corcoran M, Bostrom M, et al. Oral contraceptives - time to change the message. JAMA 1989;

If you **MISS 3 OR MORE** white "active" pills in a row (during the first 3 weeks):

- 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.
- If you are a Day 1 Starter:** **THROW OUT** the rest of the pill pack and start a new pack 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 healthcare professional because you might be pregnant.

3. You **COULD BECOME PREGNANT** if you have sex in the **7 days** after you miss pills. You **MUST** use another birth control method (such as condoms or spermicide) as a back-up method for those 7 days.

A REMINDER

If you forget any of the 7 green "reminder" pills in Week 4, **THROW AWAY** the pills you missed. Keep taking 1 pill each day until the pack is empty. You do not need a back-up method.

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

Use a **BACK-UP METHOD** anytime you have sex.

KEEP TAKING ONE "ACTIVE" PILL EACH DAY until you can reach your healthcare professional.

INSTRUCTIONS FOR USE

DIALPAK® Tablet Dispenser

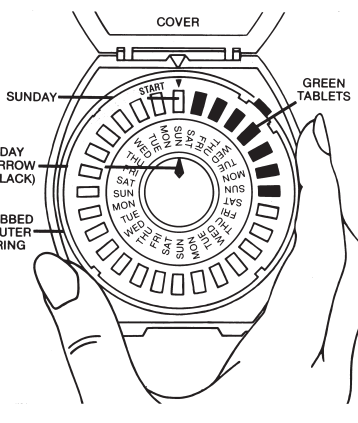
- The DIALPAK comes to you set up for Sunday Start. If your physician has instructed you to start pill-taking on the first SUNDAY after your menstrual period has begun, see directions in Number 3.
- If you are to start pill-taking on a day other than SUNDAY, the enclosed calendar label has been provided. On the calendar printed on the plastic in the center of the DIALPAK. To put label in place, identify your correct starting day, locate that day on the label, line that day up with the pill to which the word **START** and the black Day Arrow are pointing, remove the label from the backing and press the label over the printed calendar on the center plastic.

3. When the compact is open with the cover at top, the pills should be arranged as they are in the picture. If not, turn the ribbed outer ring until the pills are positioned correctly.

ORTHO-NOVUM 7/7/7: There are 7 white "active" pills, 7 light peach "active" pills, 7 peach "active" pills and 7 green "reminder" pills.

ORTHO-NOVUM 1/3/5: There are 21 peach "active" pills and 7 green "reminder" pills.

MODICON: There are 21 white "active" pills and 7 green "reminder" pills.



- The first pill you will take is indicated by **START** and lines up with the black Day Arrow in the center of the DIALPAK. If not, see the directions in Number 3.
- Push down on the first pill with your thumb or forefinger. The pill will come out through a hole in the back of the package.
- The next day, turn the DIAL to the right using the ribbed outer ring to the next pill and your second pill is ready to be taken.
- After you have taken all 21 pills, take one green "reminder" pill daily for 7 days. During this time your period should begin.
- After you have taken all the pills, start a new pack of pills even if your period is not yet over.

HOW TO INSERT REFILL (ORTHO-NOVUM 7/7/7 ONLY)

- Lift the empty refill out of the DIALPAK. Insert the new refill by placing the black tab on refill into the opening in the ribbed outer ring of the DIALPAK (see drawing).
- Press the refill down so that it fits firmly under the rib. The DIAL should be turned by the ribbed outer ring so that the arrows are again arranged as in the drawing. The first white tablet will be directly over the black DAY ARROW.

DETAILED PATIENT LABELING

PLEASE NOTE: This labeling is revised from time to time as important new medical information becomes available. Therefore, please review this labeling carefully.

The following oral contraceptive products contain a combination of an estrogen and progestogen, the two kinds of female hormones:

ORTHO-NOVUM® 7/7/7

Each white tablet contains 0.5 mg norethindrone and 0.035 mg ethinyl estradiol. Each light peach tablet contains 0.75 mg norethindrone and 0.035 mg ethinyl estradiol. Each peach tablet contains 1 mg norethindrone and 0.035 mg ethinyl estradiol. Each green tablet contains inert ingredients.

ORTHO-NOVUM® 1/3/5

Each peach tablet contains 1 mg norethindrone and 0.035 mg ethinyl estradiol. Each green tablet contains inert ingredients.

MODICON®

Each white tablet contains 0.5 mg norethindrone and 0.035 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 patient 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 works as effective as possible. However, this labeling is not a replacement for a careful discussion between you and your healthcare professional. You should discuss the information provided in this labeling with him or her, both when you first start taking the pill and during your visits. You should also follow your healthcare professional'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 without missing any pills, the chance of becoming pregnant is approximately 1% (1 pregnancy per 100 women per year of use). Typical failure rates are approximately 5% per year including women who do not always take the pills exactly as directed. 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:

Implant: <1%	Male sterilization: <1%
Injection: <1%	Cervical Cap with spermicides: 20 to 40%
IUD: 1 to 2%	Condom alone (male): 14%
Diaphragm with spermicides: 20%	Condom alone (female): 21%
Spermicides alone: 29%	Periodic abstinence: 25%
Vaginal sponge: 20 to 40%	Withdrawal: 19%
Female sterilization: <1%	No methods: 85%

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 have any of the following conditions:

- A history of heart attack or stroke
- 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 or vagina
- Unexplained vaginal bleeding (until a diagnosis is reached by your healthcare professional)
- 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
- Valvular heart disease with complications
- Severe hypertension
- Diabetes with vascular involvement
- Headaches with focal neurological symptoms
- If you plan to have surgery with prolonged bedrest
- Hypersensitivity to any component of this product.

Tell your healthcare professional if you have ever had any of these conditions. Your healthcare professional can recommend a safer method of birth control.

OTHER CONSIDERATIONS BEFORE TAKING ORAL CONTRACEPTIVES

Tell your healthcare professional if you have or have 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
- Menstrual 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 professional if they choose to use oral contraceptives.

Also, be sure to inform your healthcare professional if you smoke or are on any 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 legs can cause thrombophlebitis and a clot that travels to the lungs can cause sudden blockage of the vessel carrying blood to the lungs. Flare-ups 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 injury or have a recently delivered baby, you may be at risk of developing blood clots. You should consult your healthcare professional about stopping oral contraceptives three to four weeks before surgery and not taking oral contraceptives for two weeks after surgery or staying in bed. 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 or four weeks after a second trimester abortion. If you are breast feeding, you should wait until you have weaned your child before using the pill. (See also the section on Breast Feeding in General Precautions.)

The risk of circulatory disease in oral contraceptive users may be higher in users of high dose pills and may be greater of 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.

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, some studies report an increased risk of developing liver cancer. However, liver cancers are rare.

5. Cancer of the reproductive organs and breasts

Various studies give conflicting reports on the relationship between breast cancer and oral contraceptive use. Oral contraceptive use may slightly increase your chance of having breast cancer diagnosed, particularly after using hormonal contraceptives at a younger age. After you stop using hormonal contraceptives, the chances of having breast cancer diagnosed begin to go back down. You should have regular breast examinations by a healthcare professional and examine your own breasts monthly. Tell your healthcare professional 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 the pill may cause such cancers.

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 NON-STERILE WOMEN, BY FERTILITY CONTROL METHOD ACCORDING TO AGE	15-19	20-24	25-29	30-34	35-39	40-44
Method of control and outcome						
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 children, 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 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 29 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 do not smoke should not take oral contraceptives is based on information from older, higher-dose pills. An Advisory Committee of the FDA discussed this issue in 1989 and recommended that the benefits of low-dose oral contraceptive use by healthy, non-smoking women over 40 years of age may outweigh the possible risks.

WARNING SIGNALS

If any of these adverse effects occur while you are taking oral contraceptives, call your healthcare professional 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 healthcare professional 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

- 1. Irregular 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 that is a flow more like a normal 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 require medical attention. 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 healthcare professional.
- 2. Contact lenses**
If you wear contact lenses and notice a change in vision or an inability to wear your lenses, contact your healthcare professional.
- 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 professional.
- 4. Melasma**
A spotty darkening of the skin is possible, particularly of the face, which may persist.
- 5. Other side effects**
Other side effects may include nausea and vomiting, change in appetite, 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 professional.

GENERAL PRECAUTIONS

- 1. Missed periods and use of oral contraceptives before or during early pregnancy**
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 professional.
- 2. While breast feeding**
If you are breast feeding, consult your healthcare professional 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 engorgement. In addition, combination oral contraceptives may decrease the amount and quality of your milk. If possible, do not use combination oral contraceptives while breast feeding. You should use another method of contraception since breast feeding provides only partial protection against becoming pregnant and this partial protection decreases significantly as you breast feed for longer periods of time. You should consider starting combination oral contraceptives only after you have weaned your child completely.
- 3. Laboratory tests**
If you are scheduled for any laboratory tests, tell your healthcare professional 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, topiramate (TOPAMAX)), carbamazepine (Tegretol® is one brand of this drug), phenytoin (Dilantin® is one brand of this drug), phenylbutazone (Butazolidin® is one brand), and the drugs used in the treatment of HIV or AIDS, and possibly certain antibiotics. Medicine for pulmonary hypertension, such as bosentan (Tracleer®). 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. Hormonal contraceptives may interact with lamotrigine (LAMICTAL™), an anticonvulsant used for epilepsy. This may increase the risk of seizures so your healthcare professional may need to adjust the dose of lamotrigine. You may need to use additional contraception when you take other products which can make oral contraceptives less effective. Be sure to tell your healthcare professional 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.

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 have reported that oral contraceptives might be associated with birth defects, but these findings have not been seen in more recent studies. Nevertheless, oral contraceptives should not be used during pregnancy. You should check with your healthcare professional about risks to your unborn child of any medication taken during pregnancy.

2. Before you start taking your pills

BEFORE YOU START TAKING YOUR PILLS: It is important to take it at about the same time every day.

LOOK AT YOUR PILL PACK: The pill pack has 21 "active" pills (with hormones) to take for 3 weeks. This is followed by 1 week of green "reminder" pills (without hormones).

ORTHO-NOVUM 7/7/7: There are 7 white "active" pills, 7 light peach "active" pills, 7 peach "active" pills and 7 green "reminder" pills.

ORTHO-NOVUM 1/3/5: There are 21 peach "active" pills and 7 green "reminder" pills.

MODICON: There are 21 white "active" pills and 7 green "reminder" pills.

ALSO FIND:

- 1) where on the pack to start taking pills,
- 2) in what order to take the pills.

CHECK PICTURE OF PILL PACK AND ADDITIONAL INSTRUCTIONS FOR USING THIS PACKAGE IN THE BRIEF SUMMARY PATIENT PACKAGE INSERT.

BE SURE YOU HAVE READY AT ALL TIMES: ANOTHER KIND OF BIRTH CONTROL (such as condoms or spermicide) to use as a back-up method in case you miss pills.

AN EXTRA, FULL PILL PACK

HOW TO TAKE THE PILL

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 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 professional.
- 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, OR IF YOU TAKE SOME MEDICINES,** including some antibiotics, your pills may not work as well. Use a back-up method (such as condoms or spermicide) until you check with your healthcare professional.
- 6. IF YOU HAVE TROUBLE REMEMBERING TO TAKE THE PILL,** talk to your healthcare professional about how to make pill-taking easier or about using another method of birth control.
- 7. IF YOU HAVE ANY QUESTIONS OR ARE UNSURE ABOUT THE INFORMATION IN THIS LEAFLET,** call your healthcare professional.

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:** The pill pack has 21 "active" pills (with hormones) to take for 3 weeks. This is followed by 1 week of green "reminder" pills (without hormones).
- ORTHO-NOVUM 7/7/7:** There are 7 white "active" pills, 7 light peach "active" pills, 7 peach "active" pills and 7 green "reminder" pills.
- ORTHO-NOVUM 1/3/5:** There are 21 peach "active" pills and 7 green "reminder" pills.
- MODICON:** There are 21 white "active" pills and 7 green "reminder" pills.
- ALSO FIND:**
 - 1) where on the pack to start taking pills,
 - 2) in what order to take the pills.

CHECK PICTURE OF PILL PACK AND ADDITIONAL INSTRUCTIONS FOR USING THIS PACKAGE IN THE BRIEF SUMMARY PATIENT PACKAGE INSERT.

BE SURE YOU HAVE READY AT ALL TIMES: ANOTHER KIND OF BIRTH CONTROL (such as condoms or spermicide) to use as a back-up method in case you miss pills.

AN EXTRA, FULL PILL PACK

WHEN TO START THE FIRST PACK OF PILLS

You have a choice of which day to start taking your first pack of pills. **ORTHO-NOVUM 7/7/7, ORTHO-NOVUM 1/3/5, and MODICON** are available in the DIALPAK® Tablet Dispenser which is preset for a Sunday Start. Day 1 Start is also provided. Decide with your healthcare professional which is the best day for you. Pick a time of day which will be easy to remember.

SUNDAY START:

ORTHO-NOVUM 7/7/7: Take the first white "active" pill of the first pack on the **Sunday after your period starts** or if you are still bleeding. If your period begins on Sunday, start the pack the same day.

ORTHO-NOVUM 1/3/5: Take the first peach "active" pill of the first pack on the **Sunday after your period starts**, even if you are still bleeding. If your period begins on Sunday, start the pack the same day.

MODICON: Take the first white "active" pill of the first pack on the **Sunday after your period starts**, even if you are still bleeding. If your period begins on Sunday, start the pack the same day.

Use another method of birth control such as condoms or spermicide as a back-up method if you have sex anytime from the Sunday you start your first pack until the next **Sunday (7 days)**.

DAY 1 START:

ORTHO-NOVUM 7/7/7: Take the first white "active" pill of the first pack during the first 24 hours of your period.

ORTHO-NOVUM 1/3/5: Take the first peach "active" pill of the first pack during the first 24 hours of your period.

MODICON: Take the first white "active" pill of the first pack during the first 24 hours of your period.

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.

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 stop 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 green "reminder" pill. Do not wait any days between packs.

WHAT TO DO IF YOU MISS PILLS

ORTHO-NOVUM 7/7/7: If you **MISS 1** white, light peach, or peach "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** white or light peach "active" 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 miss pills. You **MUST** use another birth control method (such as condoms or spermicide) as a back-up method for those 7 days.

If you **MISS 2** peach "active" pills in a row in **THE 3RD WEEK:**

- 1a. 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.
- 1b. If you are a **Day 1 Starter:** **THROW OUT** the rest of the pill pack and start a new pack 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 healthcare professional because you might be pregnant.
3. You **COULD BECOME PREGNANT** if you have sex in the **7 days** after you miss pills. You **MUST** use another birth control method (such as condoms or spermicide) as a back-up method for those 7 days.

If you **MISS 3 OR MORE** white, light peach, or peach "active" pills in a row (during the first 3 weeks):

- 1a. 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.
- 1b. If you are a **Day 1 Starter:** **THROW OUT** the rest of the pill pack and start a new pack 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 healthcare professional because you might be pregnant.
3. You **COULD BECOME PREGNANT** if you have sex in the **7 days** after you miss pills. You **MUST** use another birth control method (such as condoms or spermicide) as a back-up method for those 7 days.

If you **MISS 3 OR MORE** peach "active" pills in a row in **THE 3RD WEEK:**

- 1a. 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.
- 1b. If you are a **Day 1 Starter:** **THROW OUT** the rest of the pill pack and start a new pack 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 healthcare professional because you might be pregnant.
3. You **COULD BECOME PREGNANT** if you have sex in the **7 days** after you miss pills. You **MUST** use another birth control method (such as condoms or spermicide) as a back-up method for those 7 days.

If you **MISS 3 OR MORE** white "active" pills in a row in **THE 3RD WEEK:**

- 1a. 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.
- 1b. If you are a **Day 1 Starter:** **THROW OUT** the rest of the pill pack and start a new pack 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 healthcare professional because you might be pregnant.
3. You **COULD BECOME PREGNANT** if you have sex in the **7 days** after you miss pills. You **MUST** use another birth control method (such as condoms or spermicide) as a back-up method for those 7 days.

If you **MISS 1** white "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** white "active" 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 miss pills. You **MUST** use another birth control method (such as condoms or spermicide) as a back-up method for those 7 days.

If you **MISS 2** peach "active" pills in a row in **THE 3RD WEEK:**

- 1a. 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.
- 1b. If you are a **Day 1 Starter:** **THROW OUT** the rest of the pill pack and start a new pack 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 healthcare professional because you might be pregnant.
3. You **COULD BECOME PREGNANT** if you have sex in the **7 days** after you miss pills. You **MUST** use another birth control method (such as condoms or spermicide) as a back-up method for those 7 days.

If you **MISS 3 OR MORE** white "active" pills in a row in **THE 3RD WEEK:**

- 1a. 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.
- 1b. If you are a **Day 1 Starter:** **THROW OUT** the rest of the pill pack and start a new pack 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 healthcare professional because you might be pregnant.
3. You **COULD BECOME PREGNANT** if you have sex in the **7 days** after you miss pills. You **MUST** use another birth control method (such as condoms or spermicide) as a back-up method for those 7 days.

If you **MISS 1** white "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** white "active" 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 miss pills. You **MUST** use another birth control method (such as condoms or spermicide)