

increased risk for thromboembolism. When the tablets are administered in the postpartum period, the increased risk of thromboembolic disease associated with the postpartum period must be considered (see “**Contraindications**,” “**Warnings**,” and “**Precautions**” concerning thromboembolic disease). The patient should be advised to use a non-hormonal back-up method for the first 7 days of tablet-taking. However, if intercourse has already occurred, the possibility of ovulation and conception prior to initiation of medication should be considered. OVCON 35 Fe may be initiated after a first-trimester abortion; if the patient starts OVCON 35 Fe immediately, additional contraceptive measures are not needed.

For additional patient instructions regarding complete dosing instructions, see the “HOW TO TAKE THE PILL” section in the **DETAILED PATIENT LABELING**.

HOW SUPPLIED

OVCON® 35 Fe (norethindrone and ethinyl estradiol tablets, chewable and ferrous fumarate tablets) is available only in a 28-day regimen. Each package contains 21 round, white tablets of 0.4 mg norethindrone and 0.035 mg ethinyl estradiol, imprinted with **W|C** on one side and **581** on the other. Each brown, round tablet contains 75 mg ferrous fumarate, imprinted with **PD 622** on one side.

OVCON® 35 Fe

N 0430-0581-14 Carton of 5 Blister Cards of 28 Tablets Each

Store at 25° C (77° F); excursions permitted to 15° - 30° C (59° - 86° F) [see USP Controlled Room Temperature]

References are available upon request.

PATIENT BRIEF SUMMARY

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, and when taken correctly without missing any pills, have a failure rate of about 1% per year (1 pregnancy per 100 women per year of use). The typical failure rate of pill users is 5% per year when women who miss pills are included.

For the majority of women, oral contraceptives can be taken safely. But for some women oral contraceptive use is associated with certain serious diseases that can be life-threatening or may cause temporary or permanent disability or death. The risks associated with taking oral contraceptives increase significantly if you:

- Smoke
- Have high blood pressure, diabetes, high cholesterol, or are obese
- 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 be increased 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 adverse effects on the heart and blood vessels 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.

Most side effects of the pill are not serious. The most common 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 decrease or subside within the first three months of use.

The serious side effects of the pill occur very infrequently, especially if you are in good health and do not smoke. 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), lungs (pulmonary embolism), stoppage or rupture of a blood vessel in the brain (stroke), 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 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 patient information leaflet given to you with your supply of pills. Notify your healthcare provider if you notice any unusual physical disturbances while taking the pill. In addition, drugs such as rifampin, as well as some anticonvulsants and 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 combination pill provides some important noncontraceptive health 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 healthcare provider. 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 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 healthcare provider.

DOSAGE AND ADMINISTRATION

HOW TO TAKE OVCON 35 Fe IMPORTANT POINTS TO REMEMBER

BEFORE YOU START TAKING YOUR PILLS:

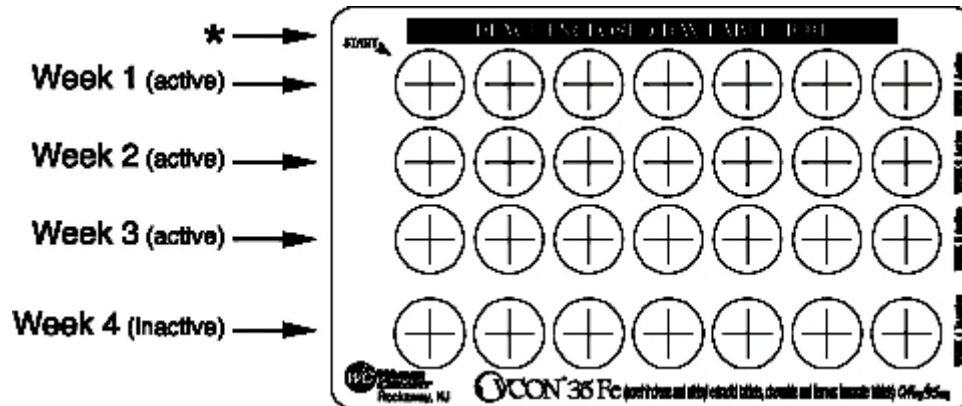
1. BE SURE TO READ THESE DIRECTIONS:
 - Before you start taking your pills
 - Anytime you are not sure what to do
2. THE PILL MAY BE SWALLOWED WHOLE OR CHEWED AND SWALLOWED. IF THE PILL IS CHEWED, YOU SHOULD DRINK A FULL GLASS (8 OUNCES) OF LIQUID IMMEDIATELY AFTER SWALLOWING.
3. TAKE ONE PILL EVERY 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.
4. 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 healthcare provider.
5. 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.
6. IF YOU HAVE VOMITING (within 3 to 4 hours after you take your pill), you should follow the instructions for WHAT TO DO IF YOU MISS PILLS. IF YOU HAVE DIARRHEA 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 of birth control (such as condoms or spermicide) until you check with your healthcare provider.
7. IF YOU HAVE TROUBLE REMEMBERING TO TAKE THE PILL, talk to your healthcare provider about how to make pill-taking easier or about using another method of birth control.
8. IF YOU HAVE ANY QUESTIONS OR ARE UNSURE ABOUT THE INFORMATION IN THIS LEAFLET, call your healthcare provider.

BEFORE YOU START TAKING YOUR PILLS

1. DECIDE WHAT TIME OF DAY YOU WANT TO TAKE YOUR PILL.
It is important to take it at about the same time every day.
2. LOOK AT YOUR PILL PACK:
The pill pack has 21 "active" white pills (with hormones) to take for 3 weeks, followed by 7

“reminder” brown pills (without hormones) to take for 1 week.

OVCON® 35 Fe
 (norethindrone and ethinyl estradiol tablets,
 chewable and ferrous fumarate tablets) 0.4mg/35mcg



*For use of day labels, see **WHEN TO START THE FIRST PACK OF PILLS.**

3. ALSO FIND:
 - o where on the pack to start taking pills,
 - o in what order to take the pills (follow the arrows), and
 - o the week numbers as shown in the picture above.
4. BE SURE YOU HAVE READY AT ALL TIMES:
 - o ANOTHER KIND OF BIRTH CONTROL (such as condoms or spermicide) to use as a back-up in case you miss pills.
 - o AN EXTRA, FULL PILL PACK.

WHEN TO START THE FIRST PACK OF PILLS

You have 2 choices of which day to start taking your first pack of pills. (See DAY 1 START or SUNDAY START directions below.) Decide with your healthcare provider which is the best day for you. Once you have decided which day you will begin taking your pills, immediately do the following: remove the Brief Summary from inside the pouch and look for the attached day label sheet; peel the label from the sheet which has the start day printed on the left hand side; place the label on the blister card in the designated location. Take your pill daily in the order indicated by the arrows on the blister card. Pick a time of day which will be easy to remember and take your pill at the same time each day.

DAY 1 START:

1. Take the first "active" white pill of the first pack during the *first 24 hours* of your period.
2. 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" white 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 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 or spermicide 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 OF YOUR OVCON 35 Fe:
Start the next pack on the day after your last brown "reminder" pill. Do not wait any days between packs.
3. WHEN YOU SWITCH FROM A DIFFERENT BRAND OF PILLS:
If your previous brand had 21 pills, wait 7 days before starting OVCON 35 Fe.
If your previous brand had 28 pills, start taking OVCON 35 Fe on the day after the last pill.

WHAT TO DO IF YOU MISS PILLS

The pill may not be as effective if you miss white "active" pills, and particularly if you miss the first few or the last few white "active" pills in a pack.

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 during the 7 *days* after you restart your pills. You MUST use a non-hormonal birth control method (such as condoms or spermicide) as a back-up for those 7 days.

If you MISS 2 white "active" pills in a row in THE 3rd WEEK:

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 healthcare provider because you might be pregnant.
3. You **COULD BECOME PREGNANT** if you have sex during the *7 days* after you restart your pills. You **MUST** use a non-hormonal birth control method (such as condoms or spermicide) as a back-up for those 7 days.

If you MISS 3 OR MORE white "active" 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 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 a non-hormonal birth control method (such as condoms or spermicide) as a back-up for the first 7 days after you restart your pills.

If you forget any of the 7 brown "reminder" 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 a back-up method.

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 "ACTIVE" (WHITE) PILL EACH DAY until you can reach your healthcare provider.

DETAILED PATIENT PACKAGE INSERT

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

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 OVCON 35 Fe properly so that it will be as effective as possible. However, this booklet is not a replacement for a careful discussion between you and your healthcare provider. You should discuss the information provided in this booklet with your healthcare

provider, both when you first start taking the pill and during your revisits. You should also follow your healthcare provider's advice with regard to regular check-ups while you are on OVCON 35 Fe.

EFFECTIVENESS OF ORAL CONTRACEPTIVES

Oral contraceptives or “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% 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 5% per year when women who miss pills are included. 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%

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 adverse effects on the heart and blood vessels 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 or have ever had 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 OVCON 35 Fe
- 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 or 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

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. Either of these can cause death or disability. 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 injury, 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 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 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 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	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 nonsmoker**	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 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 which contains the least amount of estrogen and progestin that is compatible with the individual patient needs.

WARNING SIGNALS

If any of these adverse conditions 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 healthcare provider to show you how to examine your breasts)
- Severe pain or tenderness in the stomach area (possibly indicating a 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 OVCON 35 Fe. 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 healthcare provider.

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

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 healthcare provider. 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 healthcare provider immediately to determine whether you are pregnant. Stop taking OVCON 35 Fe 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 breastfeed 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 (Tao® capsules) 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.

HOW TO TAKE OVCON 35 Fe

IMPORTANT POINTS TO REMEMBER

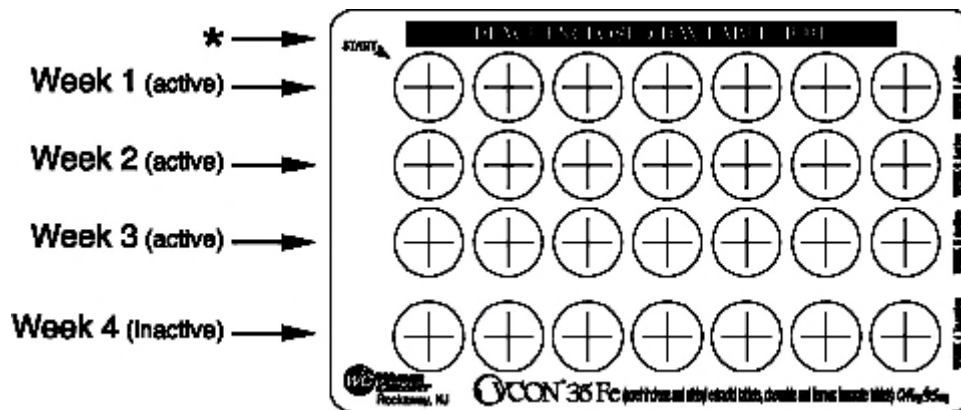
BEFORE YOU START TAKING YOUR PILLS:

1. BE SURE TO READ THESE DIRECTIONS:
 - Before you start taking your pills
 - Anytime you are not sure what to do
2. THE PILL MAY BE SWALLOWED WHOLE OR CHEWED AND SWALLOWED. IF THE PILL IS CHEWED, YOU SHOULD DRINK A FULL GLASS (8 OUNCES) OF LIQUID IMMEDIATELY AFTER SWALLOWING.
3. 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.
4. 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 healthcare provider.
5. 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.
6. IF YOU HAVE VOMITING (within 3 to 4 hours after you take your pill), you should follow the instructions for WHAT TO DO IF YOU MISS PILLS. IF YOU HAVE DIARRHEA 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 of birth control (such as condoms or spermicide) until you check with your healthcare provider.
7. IF YOU HAVE TROUBLE REMEMBERING TO TAKE THE PILL, talk to your healthcare provider about how to make pill-taking easier or about using another method of birth control.
8. IF YOU HAVE ANY QUESTIONS OR ARE UNSURE ABOUT THE INFORMATION IN THIS LEAFLET, call your healthcare provider.

BEFORE YOU START TAKING YOUR PILLS

1. DECIDE WHAT TIME OF DAY YOU WANT TO TAKE YOUR PILL.
It is important to take it at about the same time every day.
2. LOOK AT YOUR PILL PACK:
The pill *pack* has 21 "active" white pills (with hormones) to take for 3 weeks, followed by 7 "reminder" brown pills (without hormones) to take for 1 week.

OVCON® 35 Fe
(norethindrone and ethinyl estradiol tablets,
chewable and ferrous fumarate tablets) **0.4mg/35mcg**



*For use of day labels, see **WHEN TO START THE FIRST PACK OF PILLS.**

3. ALSO FIND:
 - where on the pack to start taking pills,
 - in what order to take the pills (follow the arrows), and
 - the week numbers as shown in the picture above.
4. BE SURE YOU HAVE READY AT ALL TIMES:
 - ANOTHER KIND OF BIRTH CONTROL (such as condoms or spermicide) to use as a back-up in case you miss pills.
 - AN EXTRA, FULL PILL PACK.

WHEN TO START THE FIRST PACK OF PILLS

You have 2 choices of which day to start taking your first pack of pills. (See DAY 1 START or SUNDAY START directions below.) Decide with your healthcare provider which is the best day for you. Once you have decided which day you will begin taking your pills, immediately do the following: remove the Brief Summary from inside the pouch and look for the attached day label sheet; peel the label from the sheet which has the start day printed on the left hand side; place the label on the blister card in the designated location. Take your pill daily in the order indicated by the arrows on the blister card. Pick a time of day which will be easy to remember and take your pill at the same time each day.

DAY 1 START:

1. Take the first "active" white pill of the first pack during the *first 24 hours* of your period.
2. 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" white 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 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 or spermicide 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 OF YOUR OVCON 35 Fe:
Start the next pack on the day after your last brown "reminder" pill. Do not wait any days between packs.
3. WHEN YOU SWITCH FROM A DIFFERENT BRAND OF PILLS:
If your previous brand had 21 pills, wait 7 days before starting OVCON 35 Fe.
If your previous brand had 28 pills, start taking OVCON 35 Fe on the day after the last pill.

WHAT TO DO IF YOU MISS PILLS

The pill may not be as effective if you miss white "active" pills, and particularly if you miss the first few or the last few white "active" pills in a pack.

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 during the *7 days* after you restart your pills. You MUST use a non-hormonal birth control method (such as condoms or spermicide) as a back-up for those 7 days.

If you MISS 2 white "active" pills in a row in THE 3rd WEEK:

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 healthcare provider because you might be pregnant.
3. You COULD BECOME PREGNANT if you have sex during the *7 days* after you restart your pills. You MUST use a non-hormonal birth control method (such as condoms or spermicide) as a back-up for the first 7 days after you restart your pills.

If you MISS 3 OR MORE white "active" 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 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 a non-hormonal birth control method (such as condoms or spermicide) as a back-up for the first 7 days after you restart your pills.

If you forget any of the 7 brown "reminder" 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 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 "ACTIVE" (WHITE) PILL EACH DAY until you can reach your healthcare provider.

GENERAL

1. Pregnancy due to pill failure

If taken every day as directed, the incidence of pill failure resulting in pregnancy is approximately 1% per year (one pregnancy per 100 women per year), but more typical failure rates are about 5% per year. If pregnancy 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 healthcare provider or pharmacist.

4. 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 a good medical practice 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 this 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 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
- Ovarian cysts may occur less frequently
- Ectopic (tubal) pregnancy may occur less frequently
- Noncancerous 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 healthcare provider or pharmacist. They have a more technical leaflet called the Professional Labeling, which you may wish to read.

Manufactured by: Warner Chilcott Company, Inc.

Fajardo, PR 00738

Marketed by: Warner Chilcott (US), Inc.

Rockaway, NJ 07866

