

MICROGESTIN® 1/20
(Norethindrone Acetate and Ethinyl Estradiol Tablets USP)

MICROGESTIN® Fe 1/20
(Norethindrone Acetate and Ethinyl Estradiol Tablets USP and Ferrous Fumarate Tablets*)

*Ferrous fumarate tablets are not USP for dissolution and assay.

MICROGESTIN® 1.5/30
(Norethindrone Acetate and Ethinyl Estradiol Tablets USP)

MICROGESTIN® Fe 1.5/30
(Norethindrone Acetate and Ethinyl Estradiol Tablets USP and Ferrous Fumarate Tablets*)

*Ferrous fumarate tablets are not USP for dissolution and assay.

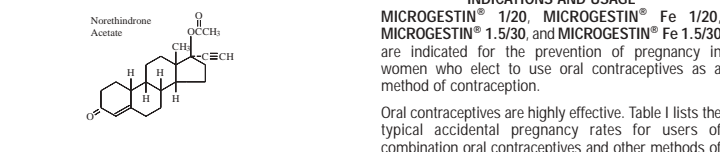
Rx only 14233

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



DESCRIPTION
MICROGESTIN® 1/20, MICROGESTIN® Fe 1/20, MICROGESTIN® 1.5/30, and MICROGESTIN® Fe 1.5/30 are progestogen-estrogen combinations.

The structural formula of norethindrone acetate (17 alpha-ethinyl-19-nortestosterone acetate) and ethinyl estradiol (17 alpha-ethinyl-1, 3, 5(10)-estratriene-3, 17 beta-diol) are as follows:



been evaluated. However, ethinyl estradiol and norethindrone may be poorly metabolized in patients with impaired liver function.

Drug-Drug Interactions
Numerous drug-drug interactions have been reported for oral contraceptives. A summary of these is found under PRECAUTIONS, Drug Interactions.

INDICATIONS AND USAGE
MICROGESTIN® 1/20, MICROGESTIN® Fe 1/20, MICROGESTIN® 1.5/30, and MICROGESTIN® Fe 1.5/30 are indicated for the prevention of pregnancy in women who elect to use oral contraceptives as a method of contraception.

Oral contraceptives are highly effective. Table I lists the typical accidental pregnancy rates for users of combination oral contraceptives and other methods of contraception. The efficacy of these contraceptive methods, except sterilization, depends upon the reliability with which they are used. Correct and consistent use of methods can result in lower failure rates.

TABLE I LOWEST EXPECTED AND TYPICAL FAILURE RATES DURING THE FIRST YEAR OF CONTINUOUS USE OF A METHOD			
Method	% of Women Experiencing an Unintended Pregnancy in the First Year of Continuous Use		
	Lowest Expected*	Typical**	Typical**
(No contraception)	(85)	(85)	3
Oral contraceptives combined	0.1	N/A***	0.8
progesterin only	0.5	N/A***	0.8
Diaphragm with spermicidal cream or jelly	6	20	20
Spermicides alone (foam, creams, gels, vaginal suppositories and vaginal film)	6	26	26
Vaginal sponge	9	20	20
Diaphragm	20	40	40
Intrauterine device	0.05	0.05	0.05
Injection	0.3	0.3	0.3
Depot medroxyprogesterone acetate	0.3	0.3	0.3
IUD	1.5	2.0	2.0
progesterone T	0.6	0.8	0.8
copper T 380A	0.1	0.1	0.1
LNG 20	0.1	0.1	0.1
Condom without spermicides	5	21	21
female	3	14	14
male	1.9	25	25
Cervical Cap with spermicidal cream or jelly	4	19	19
nulliparous	9	20	20
parous	26	40	40
Periodic abstinence (all methods)	1-9	25	25
Withdrawal	4	19	19
Female sterilization	0.10	0.15	0.15
Male sterilization	0.5	0.5	0.5

Microgestin Fe 1/20 provides a continuous dosage regimen consisting of 21 white oral contraceptive tablets and 7 brown ferrous fumarate tablets. The ferrous fumarate tablets are present to facilitate ease of drug administration via a 28-day regimen, are non-hormonal, and do not serve any therapeutic purpose.

Each white tablet, for oral administration, contains 1 mg norethindrone acetate and 20 mcg ethinyl estradiol. It also contains the following inactive ingredients: anhydrous lactose, ethyl alcohol, magnesium stearate, microcrystalline cellulose, polacrillin potassium, and povidone.

Each brown tablet for oral administration contains 75 mg ferrous fumarate and anhydrous lactose, croscopvidone, magnesium stearate, and pregelatinized starch.

Microgestin Fe 1.5/30 provides a continuous dosage regimen consisting of 21 green oral contraceptive tablets and 7 brown ferrous fumarate tablets. The ferrous fumarate tablets are present to facilitate ease of drug administration via a 28-day regimen, are non-hormonal, and do not serve any therapeutic purpose.

Each green tablet, for oral administration, contains 1.5 mg norethindrone acetate and 30 mcg ethinyl estradiol. It also contains the following inactive ingredients: anhydrous lactose, ethyl alcohol, FD&C blue (a composite of D&C Yellow No. 10 and FD&C blue No. 1), magnesium stearate, microcrystalline cellulose, polacrillin potassium, and povidone.

Each brown tablet for oral administration contains 75 mg ferrous fumarate and anhydrous lactose, croscopvidone, magnesium stearate, and pregelatinized starch.

CLINICAL PHARMACOLOGY
Combination oral contraceptives act by suppression of gonadotropins. Although the primary mechanism of this action is inhibition of ovulation, other alterations 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).

Pharmacokinetics
The pharmacokinetics of norethindrone acetate and ethinyl estradiol have not been characterized; however, the following pharmacokinetic information regarding norethindrone acetate and ethinyl estradiol is taken from the literature.

Absorption
Norethindrone acetate appears to be completely and rapidly deacetylated to norethindrone after oral administration, since the disposition of norethindrone acetate is indistinguishable from that of orally administered norethindrone (1). Norethindrone acetate and ethinyl estradiol are subject to first-pass metabolism after oral dosing, resulting in an absolute bioavailability of approximately 64% for norethindrone and 43% for ethinyl estradiol (1-3).

Distribution
Volume of distribution of norethindrone and ethinyl estradiol ranges from 2 to 4 L/kg (1-3). Plasma protein binding of both steroids is extensive (>95%); norethindrone binds to both albumin and sex hormone binding globulin, whereas ethinyl estradiol binds only to albumin (4).

Metabolism
Norethindrone undergoes extensive biotransformation, primarily via reduction, followed by sulfate and glucuronide conjugation. The majority of metabolites in the circulation are sulfates, with the CYP3A4 isoenzyme of cytochrome P-450. Part of the first-pass metabolism of ethinyl estradiol is believed to occur in gastrointestinal mucosa. Ethinyl estradiol may undergo enterohepatic circulation (6).

Excretion
Norethindrone and ethinyl estradiol are excreted in both urine and feces, primarily as metabolites (5, 6). Plasma clearance values for norethindrone and ethinyl estradiol are similar (approximately 0.4 L/hr/kg) (1-3).

Special Population
Race
The effect of race on the disposition of norethindrone acetate and ethinyl estradiol has not been evaluated.

Renal Insufficiency
The effect of renal disease on the disposition of norethindrone acetate and ethinyl estradiol has not been evaluated. In premenopausal women with chronic renal failure undergoing peritoneal dialysis who received multiple doses of an oral contraceptive containing ethinyl estradiol and norethindrone, plasma ethinyl estradiol concentrations were higher and norethindrone concentrations were unchanged compared to concentrations in premenopausal women with normal renal function.

Hepatic Insufficiency
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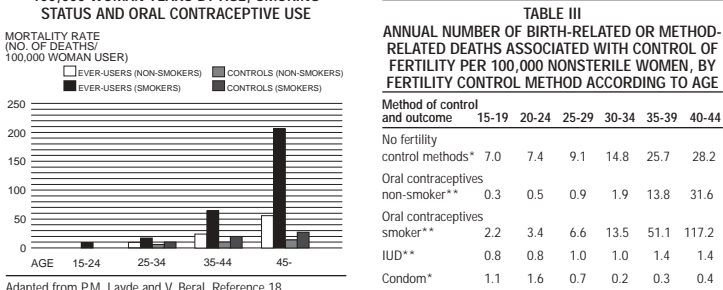
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hypertension, hypercholesterolemia, morbid obesity, and diabetes. The relative risk of heart attack for current oral contraceptive users has been estimated to be two to six (10-16). The risk is very low under the age of 30.

Smoking in combination with oral contraceptive use has been shown to contribute substantially to the incidence of myocardial infarctions in women in their mid-thirties or older with smoking accounting for the majority of excess cases (17). Mortality rates associated with circulatory disease have been shown to increase substantially in smokers over the age of 35 and non-smokers over the age of 40 (Table II) among women who use oral contraceptives.

TABLE II
CIRCULATORY DISEASE MORTALITY RATES PER 100,000 WOMAN-YEARS BY AGE, SMOKING STATUS AND ORAL CONTRACEPTIVE USE

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



Adapted from P.M. Layde and V. Beral. Reference 18.

Oral contraceptives may compound the effects of well-known risk factors, such as hypertension, diabetes, hyperlipidemias, age and obesity (19). In particular, some progestogens increase HDL cholesterol and cause glucose intolerance, while estrogens may create a state of hyperinsulinism (20-24). Oral contraceptives have been shown to increase blood pressure among users (see section 9 in WARNINGS). Similar effects on risk factors have been associated with an increased risk of heart disease. Oral contraceptives must be used with caution in women with cardiovascular disease risk factors.

b. Thromboembolism
An increased risk of thromboembolic and thrombotic disease associated with the use of oral contraceptives is well established. Case control studies have found the relative risk of venous thrombosis in women who had a first episode of superficial venous thrombosis, 4 to 11 for deep vein thrombosis or pulmonary embolism, and 1.5 to 6 for women with predisposing conditions for venous thromboembolic disease (9, 10, 25-30). Cohort studies have shown the relative risk to be somewhat lower, about 3 for new cases and about 4.5 for new cases requiring hospitalization (31). The risk of thromboembolic disease due to oral contraceptives is not related to length of use and disappears after pill use is stopped (8).

A two- to four-fold increase in relative risk of postoperative thromboembolic complications has been reported with the use of oral contraceptives (15, 32). The relative risk of venous thrombosis in women who have predisposing conditions is twice that of women without such medical conditions (15, 32). If feasible, oral contraceptives should be discontinued at least four weeks prior to and for two weeks after elective surgery of a type associated with an increase in risk of thromboembolism and during and following prolonged immobilization. Since the immediate post-partum period is also associated with an increased risk of thromboembolism, oral contraceptives should be started no earlier than four to six weeks after delivery in women who elect not to breast feed.

c. Cerebrovascular Disease
Oral contraceptives have been shown to increase both the relative and attributable risks of cerebrovascular events (thrombotic and hemorrhagic strokes), although, in general, the risk is greatest among older (>35 years), hypertensive women who also smoke. Hypertension was found to be a risk factor for both users and non-users, for both types of strokes, while smoking interacted to increase the risk for hemorrhagic strokes (33-35).

In a large study, the relative risk of thrombotic strokes has been shown to range from 3 for nonmenopausal users to 14 for users with severe hypertension (36). The relative risk of hemorrhagic stroke is reported to be 2 for non-smokers who used oral contraceptives, 2.6 for smokers who did not use oral contraceptives, 7.6 for smokers who used oral contraceptives, 1.8 for nonmenopausal users and 25.7 for users with severe hypertension (36). The attributable risk is also greater in older women (9).

d. Dose-Related Risk of Vascular Disease from Oral Contraceptives
A positive association has been observed between the amount of estrogen and progestogen in oral contraceptives and the risk of vascular disease (37-39). A decline in serum high-density lipoproteins (HDL) has been reported with many progestational agents (20-22). A decline in serum high-density lipoproteins has been associated with increased incidence of ischemic heart disease. Because estrogens increase HDL cholesterol, the net effect of an oral contraceptive depends on a balance achieved between doses of estrogen and progestin and the nature of the progestin used in the contraceptives. The amount and activity of both hormones should be considered in the choice of an oral contraceptive.

Minimizing exposure to estrogen and progestogen is in keeping with good principles of therapeutics. For any particular oral contraceptive, the dosage regimen prescribed should be one which contains the least amount of estrogen and progestogen that is compatible with a low risk of pregnancy in nonusers. Users of oral contraceptive agents should be started on preparations containing the lowest dose of estrogen which produces satisfactory results for the patient.

e. Persistence of Risk of Vascular Disease
There are two studies which have shown persistence of risk of vascular disease for ever-users of oral contraceptives. In a study in the United States, the risk of developing myocardial infarction after discontinuing oral contraceptives persists for at least 9 years for women 40 to 49 years who had used oral contraceptives for 5 or more years, but this increased risk was not demonstrated in other age groups (14). In another study in Great Britain, the risk of developing cerebrovascular disease persisted for at least 6 years after discontinuation of oral contraceptives, although excess risk was very small (40). However, both studies were performed with oral contraceptive formulations containing 50 mcg or higher of estrogens.

A small proportion of women will have persistent hypertriglyceridemia while on the pill. As discussed earlier (see WARNINGS 1a, and 1d), changes in serum triglycerides and lipoprotein levels have been reported in oral contraceptive users.

9. Elevated Blood Pressure
An increase in blood pressure has been reported in women taking oral contraceptives (74) and this increase is more likely in older oral contraceptive users (75) and with continued use (74). Data from the Royal College of General Practitioners (19) and subsequent randomized trials have shown that the incidence of hypertension increases with increasing concentrations of progestogens.

Women with a history of hypertension or hypertension-related diseases, or renal disease (76) should be encouraged to use another method of contraception. If women elect to use oral contraceptives, they should be monitored closely and if significant elevation of blood pressure occurs, oral contraceptives should be discontinued. For most women, elevated blood pressure will return to normal after stopping oral contraceptives (75), and there is no difference in the occurrence of hypertension among ever and never users (74,76,77).

10. Headache
The onset or exacerbation of migraine or development of headache with a new pattern which is recurrent, persistent, or severe requires discontinuation of oral contraceptives and evaluation of the cause.

11. Bleeding Irregularities
Breakthrough bleeding and spotting are sometimes encountered in patients on oral contraceptives, especially during the first three months of use. Non-hormonal causes should be considered, and adequate diagnostic measures taken to rule out malignancy or pregnancy in the event of breakthrough bleeding, as in the case of any abnormal vaginal bleeding. If pathology has been excluded, time or a change to another formulation may solve the problem. In the event of amenorrhea, pregnancy should be ruled out.

Some women may encounter post-pill amenorrhea or oligomenorrhea, especially when such a condition was pre-existent.

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

2. Physical Examination and Follow-Up
It is good medical practice for all women to have annual history and physical examinations, including women using oral contraceptives. The physical examination, however, may be deferred until after initiation of oral contraceptives if requested by the woman and judged appropriate by the clinician. The physical examination should include special reference to blood pressure, breasts, abdomen, and pelvic organs, including cervical cytology, and relevant laboratory tests. In case of undiagnosed, persistent or recurrent abnormal vaginal bleeding, appropriate measures should be conducted to rule out malignancy. Women with a strong family history of breast cancer or who have breast nodules should be monitored with particular care.

3. Lipid Disorders
Women who are being treated for hyperlipidemia should be followed closely if they elect to use oral contraceptives. Some progestogens may elevate LDL levels and may render the control of hyperlipidemias more difficult.

4. Liver Function
If jaundice develops in any woman receiving such drugs, the medication should be discontinued. Steroid hormones may be poorly metabolized in patients with impaired liver function.

5. Fluid Retention
Oral contraceptives may cause some degree of fluid retention. They should be prescribed with caution, and only with careful monitoring, in patients with conditions which might be aggravated by fluid retention.

6. Emotional Disorders
Women with a history of depression should be carefully observed and the drug discontinued if depression recurs to a serious degree.

7. Contact Lenses
Contact lens wearers who develop visual changes or changes in lens tolerance should be assessed by an ophthalmologist.

8. Drug Interactions
Effects of Other Drugs on Oral Contraceptives (78)
Rifampin: Metabolism of both norethindrone and ethinyl estradiol is increased by rifampin. A reduction in contraceptive effectiveness and increased incidence of breakthrough bleeding and menstrual irregularities have been associated with concomitant use of rifampin.

Anticonvulsants: Anticonvulsants such as phenobarbital, phenytoin, and carbamazepine, have been shown to increase the metabolism of ethinyl estradiol and/or norethindrone, which could result in a reduction in contraceptive effectiveness.

Trogilazine: Administration of troglitazone with an oral contraceptive containing ethinyl estradiol and norethindrone reduced the plasma concentrations of both by approximately 30%, which could result in a reduction of contraceptive effectiveness.

Antibiotics: Pregnancy while taking oral contraceptives has been reported when the oral contraceptives were administered with antimicrobials such as ampicillin, tetracycline, and griseofulvin. However, clinical pharmacokinetic studies have not demonstrated any consistent effect of antibiotics (other than rifampin) on plasma concentrations of synthetic steroids.

Atorvastatin: Coadministration of atorvastatin and an oral contraceptive resulted in AUC values for norethindrone and ethinyl estradiol by approximately 30% and 20%, respectively.

Other: Aspiric acid and acetaminophen may increase plasma ethinyl estradiol concentrations, possibly by inhibiting its metabolism. A reduction in contraceptive effectiveness and increased incidence of breakthrough bleeding has been suggested with phenylbutazone.

Effects of Oral Contraceptives on Other Drugs
Oral contraceptive combinations containing ethinyl estradiol may inhibit the metabolism of other compounds. Increased plasma concentrations of cyclosporine, prednisolone, and theophylline have been reported with concomitant administration of oral contraceptives. In addition, oral contraceptives may induce the conjugation of other compounds. Decreased plasma concentrations of acetaminophen and increased clearance of temazepam, salicylic acid, morphine, and clofibrate acid have been noted when these drugs were administered with oral contraceptives.

9. Interactions With Laboratory Tests
Certain endocrine and liver function tests and blood components may be affected by oral contraceptives:
a. Intra- and extrahepatic cholestasis
b. X-ray decreased antithrombin 3; increased norepinephrine-induced platelet aggregability.
c. Increased thyroid binding globulin (TBG) leading to increased circulating total thyroid hormone, as measured by protein-bound iodine (PBI), T₄ by column or by radioimmunoassay. Free T₄ resin uptake is decreased, reflecting the elevated TBG; free T₄ concentration is unaltered.
d. Other binding proteins may be elevated in concentration.
e. Sex-binding globulins are increased and result in elevated levels of total circulating sex steroids and corticoids; however, free or biologically active levels remain unchanged.
f. Triglycerides may be increased.
g. Glucose tolerance may be decreased.
g. Serum folate levels may be depressed by oral contraceptive therapy. This may be of clinical significance if a woman becomes pregnant shortly after discontinuing oral contraceptives.

10. Carcinogenesis
See WARNINGS section.

11. Pregnancy
Pregnancy Category X.
See CONTRAINDICATIONS and WARNINGS sections.

12. Nursing Mothers
Small amounts of oral contraceptive steroids have been identified in the milk of nursing mothers, and a few adverse effects on the child have been reported, including jaundice and breast enlargement. In addition, oral contraceptives given in the postpartum period may interfere with lactation by decreasing the quantity of breast milk. If possible, the nursing mother should be advised not to use oral contraceptives but to use other forms of contraception until she has completely weaned her child.

13. Pediatric Use
Safety and efficacy of norethindrone acetate and ethinyl estradiol have been established in women of reproductive age. Safety and efficacy are expected to be the same for postpubertal adolescents under the age of 16 and for users 16 years and older. Use of this product before menarche is not indicated.

INFORMATION FOR THE PATIENT
See patient labeling printed below.

ADVERSE REACTIONS
An increased risk of the following serious adverse reactions has been associated with the use of oral contraceptives (see WARNINGS section):

- Thrombophlebitis
- Arterial thromboembolism
- Pulmonary embolism
- Myocardial infarction

- Cerebral hemorrhage
- 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, although additional confirmatory studies are needed:

- Mesenteric thrombosis
- Retinal thrombosis

The following adverse reactions have been reported in patients receiving oral contraceptives and are believed to be drug-related:

- Nausea
- Vomiting
- Gastrointestinal symptoms (such as abdominal cramps and bloating)
- Breakthrough bleeding
- Spotting
- Change in menstrual flow
- Amenorrhea
- Temporary infertility after discontinuation of treatment
- Edema
- Melasma which may persist
- Breast changes: tenderness, enlargement, secretion
- Change in weight (increase or decrease)
- Change in cervical erosion or secretion
- Diminution in lactation when given immediately postpartum
- Cholestatic jaundice
- Migraine
- Rash (allergic)
- Headaches
- Reduced tolerance to carbohydrates
- Vaginal candidiasis
- Change in corneal curvature (steepening)
- Intolerance to contact lenses

The following adverse reactions have been reported in users of oral contraceptives and the association has been neither confirmed nor refuted:

- Pre-menstrual syndrome
- Cataracts
- Changes in appetite
- Cystitis-like syndrome
- Headache
- Nervousness
- Dizziness
- Hirsutism
- Loss of scalp hair
- Erythema multiforme
- Erythema nodosum
- Hemorrhagic eruption
- Vaginitis
- Porphyria
- Impaired renal function
- Hemolytic uremic syndrome
- Budd-Chiari syndrome
- Acne
- Changes in libido
- Colitis

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
The following non-contraceptive health benefits related to the use of oral contraceptives are supported by epidemiological studies which largely utilized oral contraceptive formulations containing estrogen doses exceeding 0.035 mg of ethinyl estradiol or 0.05 mg of mestranol (79,84).

- Decreased incidence of functional ovarian cysts
- Decreased incidence of ectopic pregnancies

Effects Related to Inhibition of Ovulation:

- Decreased incidence of functional ovarian cysts
- Decreased incidence of ectopic pregnancies

Effects From Long-Term Use:

- 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

DOSAGE AND ADMINISTRATION
The tablet dispenser has been designed to make oral contraceptive dosing as easy and as convenient as possible. The tablets are arranged in three or four rows of seven tablets each, with the days of the week appearing on the tablet dispenser above the first row of tablets.

Important: The patient should be instructed to use an additional method of protection until after the first week of administration in the initial cycle when utilizing the Sunday-Start Regimen.

The possibility of ovulation and conception prior to initiation of use should be considered.

Dosage and Administration for 21-Day Dosage Regimen
To achieve

Lancet, 2: 930, 1983. 53. Brinton, L.A., et al.: Long-term use of oral contraceptives and risk of invasive cervical cancer. *Int. J. Cancer*, 38:339-344, 1986. 54. WHO Collaborative Study of Neoplasia and Oral Contraceptives: Invasive cervical cancer and combined oral contraceptives. *Brit. Med. J.*, 290:961-965, 1985. 55. Rooks, J.B., et al.: Epidemiology of hepatocellular adenoma. *Am. J. Epidemiol.*, 107:447-450, 1978. 56. Behm, N.N., et al.: Oral contraceptives and risk of invasive cervical cancer. *Int. J. Cancer*, 38:339-344, 1986. 57. Klatkins, G.: Hepatic tumors: Possible relationship to use of oral contraceptives. *Gastroenterology*, 73:386-394, 1977. 58. Henderson, B.E., et al.: Hepatocellular carcinoma and oral contraceptives. *Brit. J. Cancer*, 48:437-440, 1983. 59. Neuberger, J., D. Forman, et al.: Oral contraceptives and hepatocellular carcinoma. *Brit. Med. J.*, 292:1355-1357, 1986. 60. Forman, D., et al.: Cancer of the liver and oral contraceptives. *Brit. Med. 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The patient labeling for oral contraceptive drug products is set forth below.

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

BRIEF SUMMARY PATIENT PACKAGE INSERT

Oral contraceptives, also known as "birth control pills" or "the pill," are taken to prevent pregnancy and, when taken correctly, have a failure rate of about 1% per year when used without missing any pills. The typical failure rate of large numbers of pill users is less than 3% per year when women who miss pills are included. For most women oral contraceptives are also free of serious or unpleasant side effects. However, forgetting to take pills considerably increases the chances of pregnancy.

For the majority of women, oral contraceptives can be taken safely. But there are some women who are at high risk of developing certain serious diseases that can be life-threatening or may cause temporary or permanent disability. The risks associated with taking oral contraceptives increase significantly if you:

- Smoke
- Have 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 suspect you are pregnant or have unexplained vaginal bleeding.

Cigarette smoking increases the risk of serious cardiovascular side effects from oral contraceptive use. This risk increases with age and with heavy smoking (15 or more cigarettes per day) and is quite marked in women over 35 years of age. Women who use oral contraceptives are strongly advised not to smoke.

Most side effects of the pill are not serious. The most common side effects are nausea, vomiting, bleeding between menstrual periods, weight gain, breast tenderness, and difficulty wearing contact lenses. These side effects, especially nausea, vomiting, and breakthrough bleeding, may 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 are young. However, you should be aware 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.

2. Liver tumors, which may rupture and cause severe bleeding. A possible but not definite association has been found with the pill and liver cancer. However, liver cancers are extremely rare. The chance of developing liver cancer from using the pill is thus even rarer.
3. High blood pressure, although blood pressure usually returns to normal when the pill is stopped.

The symptoms associated with these serious side effects are discussed in the detailed leaflet given to you with your supply of pills. Notify your doctor or health care provider if you notice any unusual physical disturbances while taking the pill. In addition, drugs such as rifampin, as well as some anticonvulsants and some antibiotics, may decrease oral contraceptive effectiveness.

Most of the studies to date on breast cancer and pill use have found no increase in the risk of developing breast cancer, although some studies have reported an increased risk of women. However, some studies have found an increase in the risk of developing cancer of the cervix in women taking the pill but this finding may be related to differences in sexual behavior or other factors not related to use of the pill. Therefore, there is insufficient evidence to rule out the possibility that the pill may cause cancer of the breast or cervix.

Taking the pill provides some important non-contraceptive benefits. These include less painful menstruation, less menstrual blood loss and anemia, fewer pelvic infections, and fewer cancers of the ovary and the lining of the uterus.

Be sure to discuss any medical condition you may have with your health care provider. Your health care provider will take a medical and family history and examine you before prescribing oral contraceptives. The physical examination may be delayed to another time if you request it and your health care provider believes that it is a good medical practice to postpone it. You should be re-examined 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 health care provider.

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

INSTRUCTIONS TO PATIENT

The Microgestin tablet dispenser has been designed to make oral contraceptive dosing as easy and as convenient as possible. The tablets are arranged in three or four rows of seven tablets each, with the days of the week appearing on the tablet dispenser above the first row of tablets.

If your tablet dispenser contains 21 white tablets, you are taking MICROGESTIN 1/20. If your tablet dispenser contains 21 white tablets and 7 brown tablets, you are taking MICROGESTIN Fe 1/20.

Each white tablet contains 1 mg norethindrone acetate and 20 mcg ethinyl estradiol.

Each brown tablet contains 75 mg ferrous fumarate, and is intended to help you remember to take the tablets correctly. These brown tablets are not intended to have any health benefit.

If your tablet dispenser contains 21 green tablets, you are taking MICROGESTIN 1.5/30. If your tablet dispenser contains 21 green tablets and 7 brown tablets, you are taking MICROGESTIN Fe 1.5/30.

Each green tablet contains 1.5 mg norethindrone acetate and 30 mcg ethinyl estradiol.

Each brown tablet contains 75 mg ferrous fumarate, and is intended to help you remember to take the tablets correctly. These brown tablets are not intended to have any health benefit.

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