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acquired pneumonia due to penicillin-resistant *S. pneumoniae* (MIC value for penicillin ≥2 µg/mL) were identified. Of the 18 levofloxacin-treated patients, 15 were evaluable following the completion of therapy. Fifteen out of the 15 evaluable levofloxacin-treated patients with community-acquired pneumonia due to penicillin-resistant *S. pneumoniae* achieved clinical success (cure or improvement). Of these 15 patients, 6 were bacteremic and 5 were classified as having severe disease. Of the 4 comparator-treated patients with community-acquired pneumonia due to penicillin-resistant *S. pneumoniae*, 3 were evaluable for clinical efficacy. Three out of the 3 evaluable comparator-treated patients achieved clinical success. All three of the comparator-treated patients were bacteremic and had disease classified as severe.

Complicated Skin And Skin Structure Infections

Three hundred ninety-nine patients were enrolled in an open-label, randomized, comparitive study for complicated skin and skin structure infections. The patients were randomized to receive either levofloxacin 750mg QD (IV followed by oral), or an approved comparator for a median of 10 ± 4.7 days. As is expected in complicated skin and skin structure infections, surgical procedures were performed in the levofloxacin and comparator groups. Surgery (incision and drainage or debridement) was performed on 45% of the levofloxacin treated patients and 44% of the comparator treated patients, either shortly before or during antibiotic treatment and formed an integral part of therapy for this indication.

Among those who could be evaluated clinically 2-5 days after completion of study drug, overall success rates (improved or cured) were 116/138 (84.1%) for patients treated with levofloxacin and 106/132 (80.3%) for patients treated with the comparator.

Success rates varied with the type of diagnosis ranging from 68% in patients with infected ulcers to 90% in patients with infected wounds and abscesses. These rates were equivalent to those seen with comparator drugs.

ANIMAL PHARMACOLOGY

Levofloxacin and other quinolones have been shown to cause arthropathy in immature animals of most species tested. (See **WARNINGS**.) In immature dogs (4–5 months old), oral doses of 10 mg/kg/day for 7 days and intravenous doses of 4 mg/kg/day for 14 days of levofloxacin resulted in arthropathic lesions. Administration at oral doses of 300 mg/kg/day for 7 days and intravenous doses of 60 mg/kg/day for 4 weeks produced arthropathy in juvenile rats.

When tested in a mouse ear swelling bioassay, levofloxacin exhibited phototoxicity similar in magnitude to ofloxacin, but less phototoxicity than other quinolones.

While crystalluria has been observed in some intravenous rat studies, urinary crystals are not formed in the bladder, being present only after micturition and are not associated with nephrotoxicity.

In mice, the CNS stimulatory effect of quinolones is enhanced by concomitant administration of non-steroidal anti-inflammatory drugs.

In dogs, levofloxacin administered at 6 mg/kg or higher by rapid intravenous injection produced hypotensive effects. These effects were considered to be related to histamine release.

In vitro and in vivo studies in animals indicate that levofloxacin is neither an enzyme inducer or inhibitor in the human therapeutic plasma concentration range; therefore, no drug metabolizing enzyme-related interactions with other drugs or agents are anticipated.

REFERENCES

1. National Committee for Clinical Laboratory Standards. Methods for Dilution Antimicrobial Susceptibility Tests for Bacteria That Grow Aerobically Fourth Edition. Approved Standard NCCLS Document M7-A4, Vol. 17, No. 2, NCS, Wayne, PA, January, 1997.
2. National Committee for Clinical Laboratory Standards. Performance Standards for Antimicrobial Disk Susceptibility Tests Sixth Edition. Approved Standard NCCLS Document M2-A6, Vol. 17, No. 1, NCCLS, Wayne, PA, January, 1997.

Patient Information About:

LEVAQUIN®

(levofloxacin tablets)

250 mg Tablets, 500 mg Tablets, and 750 mg Tablets

This leaflet contains important information about LEVAQUIN® (levofloxacin), and should be read completely before you begin treatment. This leaflet does not take the place of discussions with your doctor or health care professional about your medical condition or your treatment. This leaflet does not list all benefits and risks of LEVAQUIN®. The medicine described here can be prescribed only by a licensed health care professional. If you have any questions about LEVAQUIN® talk to your health care professional. Only your health care professional can determine if LEVAQUIN® is right for you.

What is LEVAQUIN?

LEVAQUIN® is a quinolone antibiotic used to treat lung, sinus, skin, and urinary tract infections caused by certain germs called bacteria. LEVAQUIN® kills many of the types of bacteria that can infect the lungs, sinuses, skin, and urinary tract and has been shown in a large number of clinical trials to be safe and effective for the treatment of bacterial infections.

Sometimes viruses rather than bacteria may infect the lungs and sinuses (for example the common cold). LEVAQUIN®, like other antibiotics, does not kill viruses.

You should contact your health care professional if you think that your condition is not improving while taking LEVAQUIN®. LEVAQUIN® Tablets are terra cotta pink for the 250 mg tablet, peach colored for the 500 mg tablet, or white for the 750 mg tablet.

How and when should I take LEVAQUIN?

LEVAQUIN® should be taken once a day for 3, 7, 10, or 14 days depending on your prescription. It should be swallowed and may be taken with or without food. Try to take the tablet at the same time each day and drink fluids liberally.

You may begin to feel better quickly; however, in order to make sure that all bacteria are killed, you should complete the full course of medication. Do not take more than the prescribed dose of LEVAQUIN® even if you missed a dose by mistake. You should not take a double dose.

Who should not take LEVAQUIN®?

You should not take LEVAQUIN® if you have ever had a severe allergic reaction to any of the group of antibiotics known as "quinolones" such as ciprofloxacin. Serious and occasionally fatal allergic reactions have been reported in patients receiving therapy with quinolones, including LEVAQUIN®.

If you are pregnant or are planning to become pregnant while taking LEVAQUIN®, talk to your health care professional before taking this medication. LEVAQUIN® is not recommended for use during pregnancy or nursing, as the effects on the unborn child or nursing infant are unknown. LEVAQUIN® is not recommended for children.

What are possible side effects of LEVAQUIN®?

LEVAQUIN® is generally well tolerated. The most common side effects caused by LEVAQUIN®, which are usually mild, include nausea, diarrhea, itching, abdominal pain, dizziness, flatulence, rash and vaginitis in women.

You should be careful about driving or operating machinery until you are sure LEVAQUIN® is not causing dizziness.

Allergic reactions have been reported in patients receiving quinolones including LEVAQUIN®, even after just one dose. If you develop hives, skin rash or other symptoms of an allergic reaction, you should stop taking this medication and call your health care professional.

Ruptures of shoulder, hand, or Achilles tendons have been reported in patients receiving quinolones, including LEVAQUIN®. If you develop pain, swelling, or rupture of a tendon you should stop taking LEVAQUIN® and contact your health care professional.

Some quinolone antibiotics have been associated with the development of phototoxicity ("sunburns" and "blistering sunburns") following exposure to sunlight or other sources of ultraviolet light such as artificial ultraviolet light used in tanning salons. LEVAQUIN® has been infrequently associated with phototoxicity. You should avoid excessive exposure to sunlight or artificial ultraviolet light while you are taking LEVAQUIN®.

If you have diabetes and you develop a hypoglycemic reaction while on LEVAQUIN, you should stop taking LEVAQUIN® and call your health care professional.

Convulsions have been reported in patients receiving quinolone antibiotics including LEVAQUIN®. If you have experienced convulsions in the past, be sure to let your physician know that you have a history of convulsions.

Quinolones, including LEVAQUIN®, may also cause central nervous system stimulation which may lead to tremors, restlessness, anxiety, lightheadedness, confusion, hallucinations, paranoia, depression, nightmares, insomnia, and rarely, suicidal thoughts or acts.

If you notice any side effects not mentioned in this leaflet or you have concerns about the side effects you are experiencing, please inform your health care professional.

For more complete information regarding levofloxacin, please refer to the full prescribing information, which may be obtained from your health care professional, pharmacist, or the Physicians Desk Reference (PDR).

What about other medicines I am taking?

Taking warfarin (Coumadin®) and LEVAQUIN® together can further predispose you to the development of bleeding problems. If you take warfarin, be sure to tell your health care professional.

Many antacids and multivitamins may interfere with the absorption of LEVAQUIN® and may prevent it from working properly. You should take LEVAQUIN® either 2 hours before or 2 hours after taking these products.

It is important to let your health care professional know all of the medicines you are using.

Other information

Take your dose of LEVAQUIN® once a day.

Complete the course of medication even if you are feeling better.

Keep this medication out of the reach of children.

This information does not take the place of discussions with your doctor or health care professional about your medical condition or your treatment.

ORTHO-McNEIL

OMP DIVISION

ORTHO-McNEIL PHARMACEUTICAL, INC.

Raritan, New Jersey, USA 08869

U.S. Patent No. 4,382,892 and U.S. Patent No. 5,053,407

7518201

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Shown in Product Identification Guide, page 329

MICRONOR® Tablets Ⓡ

(norethindrone) 0.35 mg

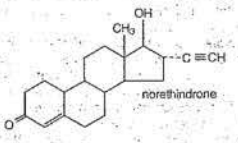
[*mīc-rō-nōr*]

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

DESCRIPTION

MICRONOR® 28 Day Regimen

Each tablet contains 0.35 mg norethindrone. Inactive ingredients include D&C Green No. 5, D&C Yellow No. 10, lactose, magnesium stearate, povidone and starch.



norethindrone

CLINICAL PHARMACOLOGY

1. MODE OF ACTION

MICRONOR progestin-only oral contraceptives prevent conception by suppressing ovulation in approximately half of users, thickening the cervical mucus to inhibit sperm penetration, lowering the midcycle LH and FSH peaks, slowing the movement of the ovum through the fallopian tubes, and altering the endometrium.

2. PHARMACOKINETICS

Serum progestin levels peak about two hours after oral administration, followed by rapid distribution and elimination. By 24 hours after drug ingestion, serum levels are near baseline, making efficacy dependent upon rigid adherence to the dosing schedule. There are large variations in serum levels among individual users. Progestin-only administration results in lower steady-state serum progestin levels and a shorter elimination half-life than concomitant administration with estrogens.

INDICATIONS AND USAGE

1. Indications

Progestin-only oral contraceptives are indicated for the prevention of pregnancy.

2. Efficacy

If used perfectly, the first-year failure rate for progestin-only oral contraceptives is 0.5%. However, the typical failure rate is estimated to be closer to 5%, due to late or omitted pills. Table 1 lists the pregnancy rates for users of all major methods of contraception.

[See table at top of next page]

CONTRAINDICATIONS

Progestin-only oral contraceptives (POPs) should not be used by women who currently have the following conditions:

- Known or suspected pregnancy
- Known or suspected carcinoma of the breast
- Undiagnosed abnormal genital bleeding
- Hypersensitivity to any component of this product
- Benign or malignant liver tumors
- Acute liver disease

WARNINGS

Cigarette smoking increases the risk of serious cardiovascular disease. Women who use oral contraceptives should be strongly advised not to smoke.

MICRONOR does not contain estrogen and, therefore, this insert does not discuss the serious health risks that have been associated with the estrogen component of combined oral contraceptives (COCs). The health care provider is referred to the prescribing information of combined oral contraceptives for a discussion of those risks. The relationship between progestin-only oral contraceptives and these risks is not fully defined. The physician should remain alert to the earliest manifestation of symptoms of any serious disease and discontinue oral contraceptive therapy when appropriate.

1. Ectopic Pregnancy

The incidence of ectopic pregnancies for progestin-only oral contraceptive users is 5 per 1000 woman-years. Up to 10% of pregnancies reported in clinical studies of progestin-only oral contraceptive users are extrauterine. Although symptoms of ectopic pregnancy should be watched for, a history of ectopic pregnancy need not be considered a contraindication to use of this contraceptive method. Health providers should be alert to the possibility of an ectopic pregnancy in women who become pregnant or complain of lower abdominal pain while on progestin-only oral contraceptives.

2. Delayed Follicular Atresia/Ovarian Cysts

If follicular development occurs, atresia of the follicle is sometimes delayed and the follicle may continue to grow beyond the size it would attain in a normal cycle. Generally these enlarged follicles disappear spontaneously. Often they are asymptomatic; in some cases they are associated with mild abdominal pain. Rarely they may twist or rupture, requiring surgical intervention.

Continued on next page

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Micronor—Cont.

3. Irregular Genital Bleeding
Irregular menstrual patterns are common among women using progestin-only oral contraceptives. If genital bleeding is suggestive of infection, malignancy or other abnormal conditions, such nonpharmacologic causes should be ruled out. If prolonged amenorrhea occurs, the possibility of pregnancy should be evaluated.
4. Carcinoma of the Breast and Reproductive Organs
Some epidemiological studies of oral contraceptive users have reported an increased relative risk of developing breast cancer, particularly at a younger age and apparently related to duration of use. These studies have predominantly involved combined oral contraceptives and there is insufficient data to determine whether the use of POPs similarly increases the risk.
A meta-analysis of 54 studies found a small increase in the frequency of having breast cancer diagnosed for women who were currently using combined oral contraceptives or had used them within the past ten years. This increase in the frequency of breast cancer diagnosis, within ten years of stopping use, was generally accounted for by cancers localized to the breast. There was no increase in the frequency of having breast cancer diagnosed ten or more years after cessation of use.
Women with breast cancer should not use oral contraceptives because the role of female hormones in breast cancer has not been fully determined.
Some studies suggest that oral contraceptive use has been associated with an increase in the risk of cervical intraepithealial neoplasia in some populations of women. However, there continues to be controversy about the extent to which such findings may be due to differences in sexual behavior and other factors. There is insufficient data to determine whether the use of POPs increases the risk of developing cervical intraepithelial neoplasia.
5. Hepatic Neoplasia
Benign hepatic adenomas are associated with combined oral contraceptive use, although the incidence of benign tumors is rare in the United States. Rupture of benign, hepatic adenomas may cause death through intraabdominal hemorrhage.
Studies have shown an increased risk of developing hepatocellular carcinoma in combined oral contraceptive users. However, these cancers are rare in the U.S. There is insufficient data to determine whether POPs increase the risk of developing hepatic neoplasia.

PRECAUTIONS

1. General
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 considered good medical practice for sexually active women using oral contraceptives to have annual history and physical examinations. The physical examination may be deferred until after initiation of oral contraceptives if requested by the woman and judged appropriate by the clinician.
3. Carbohydrate and Lipid Metabolism
Some users may experience slight deterioration in glucose tolerance, with increases in plasma insulin but women with diabetes mellitus who use progestin-only oral contraceptives do not generally experience changes in their insulin requirements. Nonetheless, prediabetic and diabetic women in particular should be carefully monitored while taking POPs.
Lipid metabolism is occasionally affected in that HDL, HDL2, and apolipoprotein A-I and A-II may be decreased; hepatic lipase may be increased. There is usually no effect on total cholesterol, HDL_3, LDL, or VLDL.
4. Drug Interactions
The effectiveness of progestin-only pills is reduced by hepatic enzyme-inducing drugs such as the anticonvulsants phenytoin, carbamazepine, and barbiturates, and the antituberculosis drug rifampin. No significant interaction has been found with broad-spectrum antibiotics.
5. Interactions with Laboratory Tests
The following endocrine tests may be affected by progestin-only oral contraceptive use:
- Sex hormone-binding globulin (SHBG) concentrations may be decreased.
- Thyroxine concentrations may be decreased, due to a decrease in thyroid binding globulin (TBG).

6. Carcinogenesis
See WARNINGS section.
7. Pregnancy
Many studies have found no effects on fetal development associated with long-term use of contraceptive doses of oral progestins. The few studies of infant growth and development that have been conducted have not demonstrated significant adverse effects. It is nonetheless prudent to rule out suspected pregnancy before initiating any hormonal contraceptive use.
8. Nursing Mothers
No adverse effects have been found on breastfeeding performance or on the health, growth or development of the infant. Small amounts of progestin pass into the breast milk, resulting in steroid levels in infant plasma of 1-6% of the levels of maternal plasma.
9. Pediatric Use
Safety and efficacy of MICRONOR Tablets 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.
10. Fertility Following Discontinuation
The limited available data indicate a rapid return of normal ovulation and fertility following discontinuation of progestin-only oral contraceptives.
11. Headache
The onset or exacerbation of migraine or development of severe headache with focal neurological symptoms which is recurrent or persistent requires discontinuation of progestin-only contraceptives and evaluation of the cause.

INFORMATION FOR THE PATIENT

1. See Detailed Patient Labeling for detailed information.
2. Counseling issues
The following points should be discussed with prospective users before prescribing progestin-only oral contraceptives:
- The necessity of taking pills at the same time every day, including throughout all bleeding episodes.
- The need to use a backup method such as condoms and spermicides for the next 48 hours whenever a progestin-only oral contraceptive is taken 3 or more hours late.
- The potential side effects of progestin-only oral contraceptives, particularly menstrual irregularities.
- The need to inform the clinician of prolonged episodes of bleeding, amenorrhea or severe abdominal pain.
- The importance of using a barrier method in addition to progestin-only oral contraceptives if a woman is at risk of contracting or transmitting STDs/HIV.

ADVERSE REACTIONS

Adverse reactions reported with the use of POPs include:
- Menstrual irregularity is the most frequently reported side effect.
- Frequent and irregular bleeding are common, while long duration of bleeding episodes and amenorrhea are less likely.
- Headache, breast tenderness, nausea, and dizziness are increased among progestin-only oral contraceptive users in some studies.
- Androgenic side effects such as acne, hirsutism, and weight gain occur rarely.

OVERDOSAGE

There have been no reports of serious ill effects from overdosage, including ingestion by children.

DOSAGE AND ADMINISTRATION

To achieve maximum contraceptive effectiveness, MICRONOR must be taken exactly as directed. One tablet is taken every day, at the same time. Administration is continuous, with no interruption between pill packs. See Detailed Patient Labeling for detailed instruction.

HOW SUPPLIED

MICRONOR Tablets are available in a DIALPAK® Tablet Dispenser (NDC 0062-1411-01) containing 28 green tablets (0.35 mg norethindrone).
STORAGE: Store at controlled room temperature (15-30°C; 59-86°F).

REFERENCE

McCann M, and Potter L. Progestin-Only Oral Contraceptives: A Comprehensive Review. Contraception, 50:60 (Suppl. 1), December 1994.

DETAILED PATIENT LABELING

MICRONOR® (norethindrone) Tablets
This product (like all oral contraceptives) is used to prevent pregnancy. It does not protect against HIV infection (AIDS) or other sexually transmitted diseases.

DESCRIPTION

MICRONOR® 28 Day Regimen
Each tablet contains 0.35 mg norethindrone. Inactive ingredients include D&C Green No. 5, D&C Yellow No. 10, lactose, magnesium stearate, povidone and starch.

TABLE I: PERCENTAGE OF WOMEN EXPERIENCING AN UNINTENDED PREGNANCY DURING THE FIRST YEAR OF TYPICAL USE AND THE FIRST YEAR OF PERFECT USE OF CONTRACEPTION AND THE PERCENTAGE CONTINUING USE AT THE END OF THE FIRST YEAR. UNITED STATES.

	% of Women Experiencing an Unintended Pregnancy within the First Year of Use		% of Women Continuing Use at One Year[3]
Method (1)	Typical Use[1] (2)	Perfect Use[2] (3)	(4)
Chance[4]	85	85	
Spermicides[5]	26	6	40
Periodic abstinence	25		63
Calendar		9	
Ovulation method		3	
Sympto-Thermal[6]		2	
Post-Ovulation		1	
Withdrawal	19	4	
Cap[7]			
Parous Women	40	26	42
Nulliparous Women	20	9	56
Sponge			
Parous Women	40	20	42
Nulliparous Women	20	9	56
Diaphragm[7]	20	6	56
Condom[8]			
Female (Reality)	21	5	56
Male	14	3	61
Pill	5		71
Progestin Only		0.5	
Combined		0.1	
IUD			
Progesterone T	2.0	1.5	81
Copper T380A	0.8	0.6	78
LNg 20	0.1	0.1	81
Depo-Provera	0.3	0.3	70
Norplant and Norplant-2	0.05	0.05	88
Female Sterilization	0.5	0.5	100
Male Sterilization	0.15	0.10	100

Adapted from Trussel J. Contraceptive efficacy. In Hatcher RA, Trussel J, Stewart F, Cates W, Stewart GK, Kowal D, Guest F, Contraceptive Technology: Seventeenth Revised Edition. New York NY: Irvington Publishers, 1998, in press.

1. Among *typical* couples who initiate use of a method (not necessarily for the first time), the percentage who experience an accidental pregnancy during the first year if they do not stop use for any other reason.
2. Among couples who initiate use of a method (not necessarily for the first time) and who use it *perfectly* (both consistently and correctly), the percentage who experience an accidental pregnancy during the first year if they do not stop use for any other reason.
3. Among couples attempting to avoid pregnancy, the percentage who continue to use a method for one year.
4. The percents becoming pregnant in columns (2) and (3) are based on data from populations where contraception is not used and from women who cease using contraception in order to become pregnant. Among such populations, about 89% become pregnant within one year. This estimate was lowered slightly (to 85%) to represent the percent who would become pregnant within one year among women now relying on reversible methods of contraception if they abandoned contraception altogether.
5. Foams, creams, gels, vaginal suppositories, and vaginal film.
6. Cervical mucus (ovulation) method supplemented by calendar in the pre-ovulatory and basal body temperature in the post-ovulatory phases.
7. With spermicidal cream or jelly.
8. Without spermicides.

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INTRODUCTION

This leaflet is about birth control pills that contain one hormone, a progestin. Please read this leaflet before you begin to take your pills. It is meant to be used along with talking with your doctor or clinic.

Progestin-only pills are often called "POPs" or "the mini-pill". POPs have less progestin than the combined birth control pill (or "the pill") which contains both an estrogen and a progestin.

HOW EFFECTIVE ARE POPs?

About 1 in 200 POP users will get pregnant in the first year if they all take POPs perfectly (that is, on time, every day). About 1 in 20 "typical" POP users (including women who are late taking pills or miss pills) gets pregnant in the first year of use. Table 2 will help you compare the efficacy of different methods.

[See table above]

HOW DO POPs WORK?

POPs can prevent pregnancy in different ways including:

- They make the cervical mucus at the entrance to the womb (the uterus) too thick for the sperm to get through to the egg.
- They prevent ovulation (release of the egg from the ovary) in about half of the cycles.
- They also affect other hormones, the fallopian tubes and the lining of the uterus.

YOU SHOULD NOT TAKE POPs

- If there is any chance you may be pregnant.
- If you have breast cancer.
- If you have bleeding between your periods that has not been diagnosed.
- If you are taking certain drugs for epilepsy (seizures) or for TB. (See "Using POPs with Other Medicines" below.)
- If you are hypersensitive, or allergic, to any component of this product.
- If you have liver tumors, either benign or cancerous.
- If you have acute liver disease.

RISKS OF TAKING POPs

Cigarette smoking greatly increases the possibility of suffering heart attacks and strokes. Women who use oral contraceptives are strongly advised not to smoke.

WARNING: If you have sudden or severe pain in your lower abdomen or stomach area, you may have an ectopic pregnancy or an ovarian cyst. If this happens, you should contact your doctor or clinic immediately.

Ectopic Pregnancy

An ectopic pregnancy is a pregnancy outside the womb. Because POPs protect against pregnancy, the chance of having a pregnancy outside the womb is very low. If you do get pregnant while taking POPs, you have a slightly higher chance that the pregnancy will be ectopic than do users of some other birth control methods.

Ovarian Cysts

These cysts are small sacs of fluid in the ovary. They are more common among POP users than among users of most other birth control methods. They usually disappear without treatment and rarely cause problems.

Cancer of the Reproductive Organs and Breasts

Some studies in women who use combined oral contraceptives that contain both estrogen and a progestin have reported an increase in the risk of developing breast cancer, particularly at a younger age and apparently related to duration of use. There is insufficient data to determine whether the use of POPs similarly increases this risk.

A meta-analysis of 54 studies found a small increase in the frequency of having breast cancer diagnosed for women who were currently using combined oral contraceptives or had used them within the past ten years. This increase in the frequency of breast cancer diagnosis, within ten years of stopping use, was generally accounted for by cancers localized to the breast. There was no increase in the frequency of having breast cancer diagnosed ten or more years after cessation of use.

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 and there is insufficient data to determine whether the use of POPs increases the risk of developing cancer of the cervix.

Liver Tumors

In rare cases, combined 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 among women who use combined oral contraceptives. However, liver cancers are rare. There is insufficient data to determine whether POPs increase the risk of liver tumors.

Diabetic Women

Diabetic women taking POPs do not generally require changes in the amount of insulin they are taking. However, your physician may monitor you more closely under these conditions.

SEXUALLY TRANSMITTED DISEASES (STDs)

WARNING: POPs do not protect against getting or giving someone HIV (AIDS) or any other STD, such as chlamydia, gonorrhea, genital warts or herpes.

SIDE EFFECTS

Irregular Bleeding:

The most common side effect of POPs is a change in menstrual bleeding. Your periods may be either early or late, and you may have some spotting between periods. Taking pills late or missing pills can result in some spotting or bleeding.

Other Side Effects:

Less common side effects include headaches, tender breasts, nausea and dizziness. Weight gain, acne and extra hair on your face and body have been reported, but are rare.

If you are concerned about any of these side effects, check with your doctor or clinic.

USING POPs WITH OTHER MEDICINES

Before taking a POP, inform your health care provider of any other medication, including over-the-counter medicine, that you may be taking.

These medicines can make POPs less effective:

Medicines for seizures such as:

- Phenytoin (Dilantin)
- Carbamazepine (Tegretol)
- Phenobarbital

Medicine for TB:

- Rifampin (Rifampicin)

Before you begin taking any new medicines be sure your doctor or clinic knows you are taking a progestin-only birth control pill.

HOW TO TAKE POPs

IMPORTANT POINTS TO REMEMBER

- POPs must be taken at the same time every day, so choose a time and then take the pill at that same time every day. Every time you take a pill late, and especially if you miss a pill, you are more likely to get pregnant.
- Start the next pack the day after the last pack is finished. There is no break between packs. Always have your next pack of pills ready.
- You may have some menstrual spotting between periods. Do not stop taking your pills if this happens.
- If you vomit soon after taking a pill, use a backup method (such as a condom and/or a spermicide) for 48 hours.
- If you want to stop taking POPs, you can do so at any time, but, if you remain sexually active and don't wish to become pregnant, be certain to use another birth control method.
- If you are not sure about how to take POPs, ask your doctor or clinic.

STARTING POPs

- It's best to take your first POP on the first day of your menstrual period.
- If you decide to take your first POP on another day, use a backup method (such as a condom and/or a spermicide) every time you have sex during the next 48 hours.
- If you have had a miscarriage or an abortion, you can start POPs the next day.

IF YOU ARE LATE OR MISS TAKING YOUR POPs

- If you are more than 3 hours late or you miss one or more POPs:

(1) **TAKE** a missed pill as soon as you remember that you missed it,

(2) **THEN** go back to taking POPs at your regular time,

(3) **BUT** be sure to use a backup method (such as a condom and/or a spermcide) every time you have sex for the next 48 hours.

- If you are not sure what to do about the pills you have missed, keep taking POPs and use a backup method until you can talk to your doctor or clinic.

IF YOU ARE BREASTFEEDING

- If you are fully breastfeeding (not giving your baby any food or formula), you may start your pills 6 weeks after delivery.

Continued on next page

TABLE II: PERCENTAGE OF WOMEN EXPERIENCING AN UNINTENDED PREGNANCY DURING THE FIRST YEAR OF TYPICAL USE AND THE FIRST YEAR OF PERFECT USE OF CONTRACEPTION AND THE PERCENTAGE CONTINUING USE AT THE END OF THE FIRST YEAR. UNITED STATES.

	% of Women Experiencing an Unintended Pregnancy within the First Year of Use		% of Women Continuing Use at One Year[3]
Method (1)	Typical Use[1] (2)	Perfect Use[2] (3)	(4)
Chance[4]	85	85	
Spermicides[5]	26	6	40
Periodic abstinence	25		63
Calendar		9	
Ovulation method		3	
Sympto-Thermal[6]		2	
Post-Ovulation		1	
Withdrawal	19	4	
Cap[7]			
Parous Women	40	26	42
Nulliparous Women	20	9	56
Sponge			
Parous Women	40	20	42
Nulliparous Women	20	9	56
Diaphragm[7]	20	6	56
Condom[8]			
Female (Reality)	21	5	56
Male	14	3	61
Pill	5		71
Progestin Only		0.5	
Combined		0.1	
IUD			
Progesterone T	2.0	1.5	81
Copper T380A	0.8	0.6	78
LNg 20	0.1	0.1	81
Depo-Provera	0.3	0.3	70
Norplant and Norplant-2	0.05	0.05	88
Female Sterilization	0.5	0.5	100
Male Sterilization	0.15	0.10	100

Adapted from Trussel J. Contraceptive efficacy. In Hatcher RA, Trussel J, Stewart F, Cates W, Stewart GK, Kowal D, Guest F, Contraceptive Technology: Seventeenth Revised Edition. New York NY: Irvington Publishers, 1998, in press.

1. Among *typical* couples who initiate use of a method (not necessarily for the first time), the percentage who experience an accidental pregnancy during the first year if they do not stop use for any other reason.
2. Among couples who initiate use of a method (not necessarily for the first time) and who use it *perfectly* (both consistently and correctly), the percentage who experience an accidental pregnancy during the first year if they do not stop use for any other reason.
3. Among couples attempting to avoid pregnancy, the percentage who continue to use a method for one year.
4. The percents becoming pregnant in columns (2) and (3) are based on data from populations where contraception is not used and from women who cease using contraception in order to become pregnant. Among such populations, about 89% become pregnant within one year. This estimate was lowered slightly (to 85%) to represent the percent who would become pregnant within one year among women now relying on reversible methods of contraception if they abandoned contraception altogether.
5. Foams, creams, gels, vaginal suppositories, and vaginal film.
6. Cervical mucous (ovulation) method supplemented by calendar in the pre-ovulatory and basal body temperature in the post-ovulatory phases.
7. With spermicidal cream or jelly.
8. Without spermicides.

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