



Oral Contraceptive

PATIENT EDUCATION SERIES

The introduction of oral contraceptives was one of the most transformative developments in the history of women's health. Since introduced in May of 1960, these pills have provided reliable contraception for millions of women throughout the world. Currently there are over 70 different brands on the market. The dosages we use today are vastly lower than those used in the original pills. While very safe and effective, today's oral contraceptives are not without side effects. This handout reviews how the pills work, side effects, and practical issues about taking this medicine.

What's in oral contraceptive pills?

The term "oral contraceptive" refer to two types of pills. The most common is a combination of estrogen and progestin: "combination oral contraceptives" (COC's). The second type of oral contraceptive, the Progestin-Only Pill, which is not quite as well known will be discussed in a separate handout.

The estrogen in most of the COC's is the same compound, ethinyl estradiol, varying from 20-50 micrograms (mcg). The pills prescribed by providers at Brown Health Services commonly have 35mcg or less of estrogen. Progestin is the second component of COC's. Pharmaceutical companies have created a number of different progestins with slightly different qualities, which has allowed a variety of COCs to be available.

The properties and side effects one might experience taking a particular pill are not simply caused by the "dose" of the hormones in that pill. There are unique interactions between the estrogen and the progestin, individual variations in absorption, metabolism, and the binding of the hormones to receptors in each person which affect the qualities one experiences with a specific pill. While most women will do well with any pill they try—some women will respond more favorably to one pill versus another.

Of note, the Nuvaring—the vaginal contraceptive ring, has the same hormones, side effects and risks as COC's. It simply utilizes a different delivery system. Nuvaring is discussed in a separate handout.

Some important definitions:

"Active pills" refer to the pills in the package that contain hormones. "Inactive" or "placebo" pills are members of the pill package that do not contain any hormone. Their presence in the pack is to help a woman stay on schedule taking her pills. Inactive pills always have a different color from the active pills.

During the days that the inactive pills are taken, a woman will likely have a period. For years, all pill packs had 21 days of active pills and 7 days of inactive pills = 28 pills creating a monthly menstrual cycle. In the last few years, many different patterns for taking active and inactive pills have been developed. You can discuss with your provider which pattern might fit your needs best. One's contraceptive protection CONTINUES during the inactive pills.

"Monophasic pills" have the same dose in all the active pills. "Triphasics" typically have 3 changes of dose in the active pills. Monophasic and triphasic pills are both effective and popular.

How do they work:

The progestins provide most of the contraceptive effect. They cause thickening of the cervical mucus which prevents sperm from entering the uterus. The progestin and estrogen together are involved in suppressing ovulation. The estrogen helps prevent irregular spotting or bleeding.

How effective are COC's:

COC's are about 98-99% effective if taken every day as directed. The effectiveness of the pill as a contraceptive drops when pills are taken late or missed.

Cost:

COC's come in generic and name brand versions. Some insurance companies cover the cost of this prescription medication in part or full, others cover only generics. Without insurance, a pack of pills can cost between \$30-\$60. Sometimes Brown's pharmacy has contracts that allow significant savings on a particular brand—check with your provider.

Side effects: Rare but Serious

COC's can make a woman more prone to forming a blood clot in a vein or artery. Different symptoms can occur depending on where the clot forms. While clots can occur in any part of the body, they are most common in the legs, abdomen, heart, lungs, eye, or in the brain. In the brain, a clot can manifest as a stroke. The risk of these events is very low in healthy young women. In the last 10 years, researchers have learned that a small percentage of the population carry genetic mutations that can make them more prone to form blood clots. These individuals are fine when left alone, but if they undergo surgery, get pregnant, are immobilized for long periods of time or take oral contraceptives,

they will form clots at a higher rate than the general population. The way that we screen for these inherited clotting disorders is to review your family history. We are particularly interested in close relatives who had a blood clot, stroke, or other clotting problems at a young age. Further tests may be ordered depending on what is gleaned from this history. Additionally, we are interested in identifying women with a specific type of migraine headache: individuals who experience migraine with aura (a temporary loss of vision, or other visual or neurological symptoms prior to onset of headache), as they may have an increased risk for stroke when taking COC's. Beside the above, risks for stroke are increased in women who are over 35 years old, women who smoke or have high blood pressure, heart disease, or diabetes.

The incidence of blood clot per 100,000 women years*

Young women—general population	4-5
COC with less than 50 mcg estrogen	12-20
Pregnant women	48-60

From Contraceptive Technology, 2007 ed.
*woman year = one year in the reproductive life of a sexually active woman.

The warning signs of a blood clot spell out the acronym ACHES:

- A Abdominal pain
- C Chest pain (also shortness of breath)
- H Headaches (especially those that are new, **severe**, associated with dizziness, fainting, difficulty speaking, numbness or weakness in extremities)
- E Eye problems (blurred vision or loss of vision)
- S Severe leg pain (or redness/swelling in calves or thigh).

IF YOU DEVELOP any of the symptoms of "ACHES" while on COC's, please CALL HEALTH SERVICES 863-3953 or 863-4111 for EMERGENCY medical attention on campus; please seek medical attention immediately if you are away from campus. Developing jaundice (yellow discoloration of your eyes or skin) also warrants a call to your provider ASAP.

Other side effects:

Pregnancy: COC's do not affect future fertility, risk of miscarriage, or birth defects.

High Blood Pressure: While most studies show that today's COC's have little impact on blood pressure, one study suggested blood pressure could rise. We like to screen our patients when starting COC's, a few months after starting, and then at their annual visits.

Liver tumors: COC's have been associated with an increased risk of forming benign liver tumors. This is a very rare occurrence, but you should contact your provider if you develop upper abdominal pain. Additionally, gallstones, which can form in the gallbladder have a slightly increased risk of developing in women taking COC's, especially with in women with a family history prone to gallstones.

Breast Cancer Risk:

A well-studied question, the literature suggests use of COC's has little if any effect on the risk of breast cancer.

Cervical Cancer Risk:

The risk of developing this type of cancer is slightly increased in COC's users. Fortunately, routine Pap smears are an excellent cancer screening tool.

Yasmin, Yaz, Ocella users

This group of pills can cause an elevated potassium in women who take certain blood pressure medications or medications like: Advil, Motrin, ibuprofen, Aleve, Naproxyn or other prescription nonsteroidal anti-inflammatory medications (NOT Tylenol) on a CONTINUOUS daily basis. Intermittent use of these medicines DOES NOT pose a problem.

Common side effects of COC's

- 1) Nausea: Some women may experience mild nausea when starting COC's. Taking the pill at night or with food may help. If this is persisting for weeks or is unusually severe, be in touch with your provider.
- 2) Breast tenderness or enlargement: This may occur in about 30% of women. A supportive bra may be very helpful. Generally this improves as your body adjusts over the first few months. If you notice a discrete lump, make an appointment to get this checked.
- 3) Headaches: If you develop new headaches while on COC's, contact your provider.

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- 4) Unscheduled spotting or breakthrough bleeding: Common the first 3 months of starting COC's, up to 50% of users may experience this. By the 3rd pack of pills, 90% of women are no longer experiencing spotting. Some women may notice some mild menstrual cramps with the spotting. This should resolve too .

IF you are experiencing light bleeding on your active pills that lasts longer than 5 days, or heavier bleeding lasting more than 3 days, please be in touch with your provider. Depending on a number of factors, we may just observe, or suggest some changes to resolve the bleeding.

NOTE: Contraceptive effectiveness is present even with spotting, as long as pills haven't been missed.

Some studies suggest smoking increases risk of spotting on COC's.

- 5) Missed periods or amenorrhea: Sometimes a woman who has taken all her pills correctly will not get her period. This can happen for a variety of reasons (stress, illness, travel, rarely thyroid or other hormonal issues). A urine pregnancy test is advised before starting a new pack of pills. If this continues to happen, a change to another COC will likely get your period back. IF you have missed pills and don't get your period, or your period is very scant, it is very important to obtain a pregnancy test.
- 6) Weight gain: 3 placebo-controlled randomized clinical studies have demonstrated COC's do not cause weight changes. However, some women may react to the hormones with more mild fluid retention of some tissue around breasts and hips. Discuss with your provider if you are experiencing this.
- 7) Mood changes: While multiple studies have not demonstrated an increase in clinical depression from COC's, some women do report changes in their emotional status such as depressive feelings or irritability. If you have a history of depression discuss this with your provider. If you feel your mood is changing while on COC's, promptly contact your provider.

- 8) Decrease in sex drive: Our sex drives are affected by almost every aspect of our lives. Fatigue, stress, emotions, and alcohol can strongly impact how interested we are in sex . The hormones in COC's may cause a decrease in sex drive in some women. If you are noticing this persistently, please be in touch. A change to another pill or another method of contraception may be considered.

- 9) Changes in vaginal discharge: A slight increase in the amount of discharge may occur in some women.. Others may notice less lubrication with intercourse. Neither change is harmful. Extra lubrication can be used as needed to make sex comfortable.

- 10) Contact lens wearer: Rarely, women who wear contacts may notice some visual changes or change in lens tolerance. Consultation with your ophthalmologist can help with this.

Benefits of COC's:

- 1) Taking COC's will regulate a woman's menstrual cycle. Some women can tell the day and time their period will begin.
- 2) Menstrual cramps become markedly reduced for most women.
- 3) Menstrual volume is significantly reduced in most pill users. A lighter period is especially beneficial to those with iron deficiency anemia.
- 4) Acne can be improved by taking COC's. While responses can vary between individuals, some women take this medicine primarily to treat their acne.
- 5) COC users have a substantially lower risk of developing ovarian cancer and uterine cancer. Breast cysts, ovarian cysts and the risk of pelvic inflammatory disease, as well as menstrual exacerbations of seizure disorders, asthma, porphyria, and sickle cell anemia are all reduced in COC users.
- 6) COC's treat many of the hormonal issues for women with Polycystic Ovarian Syndrome.

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HOW DO I OBTAIN A PRESCRIPTION?

If you are interested in starting COC's, please call to make an appointment: 863-3953. At this visit, we will discuss your medical history and family history, and check your blood pressure. Often, a gynecologic exam before prescribing COC's will not be needed, though it is advised that women age 21 and over have an annual exam.

We generally give one pack of pills at that appointment PLUS a year of refills. We advise a brief follow up appointment around the 3rd month of pills to check blood pressure. If at any time you are experiencing some concerns with your COC, don't hesitate to be in touch with your provider. If you need a refill between appointments due to a lost pack, a missed appointment, etc, don't hesitate to call in.

HOW DO I START MY PILL?

There are 3 main ways to start. For ALL of these methods, it will take 7 DAYS for your pills to be EFFECTIVE as a contraceptive. You will need to use a secondary method of contraception during these FIRST 7 DAYS: condom or abstain from intercourse. This 7 DAY period of time is only necessary during your FIRST PACK of pills. When taking the pills continuously month to month, the effectiveness remains from pack to pack. In other words, you do not need to use a backup method the first seven days of every pack, just the first month. However, we do recommend using condoms consistently with COC's to protect against sexually transmitted infections.

Traditional "Sunday Start": If your period begins on Mon, Tue, Wed, Thur, Fri, or Sat, start your pill on that Sunday. If your period starts on Sunday, start that Sunday. The only advantage is your period will occur during the week, not the weekend.

"First Day Start": Start your first pill on the first day of your next period. You will continue to have your period this first week of pills.

"Quick Start": Start your first pill on the day of your appointment. If you have had unprotected sex since your last period, you should discuss the need for emergency contraception with your clinician and also discuss if a follow up pregnancy test is advised.

Extended and continuous use of contraceptive pills: A new trend involves extending the use of active hormones continuously over several cycles, decreasing the number of times you will experience a withdrawal bleed (period). Research show that there is absolutely no harm in having fewer menstrual bleeds and many positives.

The advantages of extended use of OCPs include less period-associated discomfort (bloating, cramps, headaches, gastrointestinal upset) as well as protection against anemia.

Protection against pregnancy with extended regimens is excellent, consistent with the more traditional monthly cycling failure rate of less than 1%.

Your provider may prescribe an extended use pill product specifically designed for this use, such as Seasonale, Seasonique, Lo-Seasonique, Quartette or Lybrel. There are subtle differences among these brands, so be sure to discuss these with your provider and take the pills as directed in the package insert.

In addition, any monophasic OCP can be prescribed, with instructions from your provider to take it differently than the package insert directs. In this case, in consultation with your provider there are options to take one active tablet for 42 consecutive days (called bicycling) or 63 consecutive days (called tricycling) followed by four to seven pill-free days. Sometimes 84 pills can be taken in sequence followed by a pill free week (mimicking products like Seasonale). These various extended regimens can be repeated as long as you plan to continue taking OCs.

Unscheduled bleeding/spotting often occurs during the first few months of extended OC use, but then resolves. If troublesome unscheduled bleeding occurs after the first 21 days of hormone use, one approach is to stop the OC for three days to allow withdrawal bleeding, and then resume the pill for at least 21 days of continuous use. This approach of scheduling a short hormone-free interval can be repeated whenever bothersome breakthrough bleeding occurs, without concern about backup contraception, as long as the patient has taken at least 21 days of active pills continuously before proceeding with a hormone-free interval. Over time, breakthrough bleeding episodes should become spaced out and stop.

TAKE THE PILL EVERYDAY!!

Be aware that to be effective, the pill needs to be taken every day. The first week of pills in each pack are the MOST important in preventing you from ovulating that cycle. Try to plan carefully to pick up your prescription from the pharmacy so you have it the day you need to start. Take your pills if you go away for the weekend and on vacation. To help remember, try to link taking your pill with

or eating a certain meal or setting an alarm. It is a valuable practice to make sure you took yesterday's pill each morning.

WHAT MEDICINES WILL EFFECT MY COCs?

The following medicines DECREASE the effectiveness of COC's: Topamax, Lamictal, Tegretol, Nevirapine, Trileptal, Phenobarbital, Dilantin, Mysoline, Rifampin, St. John's Wort, Provigil, Ethosuximine, Griseofulvin, Troglitazone, Vigabatrin.

The following medicines will NOT DECREASE the effectiveness of COC's: Ampicillin, Biaxin, Cipro, Doxycycline, Diflucan,, Zarontin, Keppra, Sabril, Zonegram, Lyrica, Klonopin, Bafitril. There is a lot of conflicting information surrounding this issue. In particular, your prescription insert will list "antibiotics" as decreasing pill effectiveness. There is general agreement that the above mentioned antibiotics do not require back up methods, contrary to the product labeling.

LATE or MISSED PILLS:

Taking a pill every day is not easy; missing a pill happens. The following are simplified missed pill rules.

- If you remember your pill within 12 hours of the time that you were to take it, take it immediately and take all the rest of the pill as the usual time.
 - No back-up method is needed.
 - No emergency contraception (EC) is needed.
- If you miss 1 pill for more than 12 hours, you should take the pill you missed now together with today's pill (even if it means taking 2 pills in 1 day), and use condoms or abstinence for the next 7 days.
 - No EC is needed.
- If you miss more than 1 pill, you should take today's pill and the last forgotten pill today (2 tablets in 1 day). The rest of the instructions depend upon which pills you missed:
 - If you have at least 7 active pills in the pack you should use condoms for 7 days and use EC if you have had unprotected intercourse in the prior 7 days.
 - If you have 7 or fewer active pills in the pack, you have two options:
 1. Take the rest of the active pills. Skip the placebo pills and start the next pack of pills without interruption.
 - Use condoms or abstain for 7 days.
 2. Take the pills as in the pack.

- Use condoms or abstinence until you have taken 7 of the pills in the next pack.
- Use EC if you have had any unprotected intercourse in the prior 7 days.

What if I lose a pill?

You may replace it from a separate pack of pills; you can request a spare pack or make-up pack from your provider. Call to speak with a provider as advice may vary depending where you are in your pack and what pill you are on.

What if I am vomiting or have diarrhea?

If you vomit within 2 hours of taking a pill or have severe vomiting and diarrhea for 2 or more days, you should treat it the same as missed pills—see above but feel free to contact your provider to discuss.

Can I skip a period on purpose?

There may be a week when you want to avoid getting your period because of a special trip or event. You may accomplish this by simply NOT taking the inactive pills: throw them out and then start your next pack of pills. This works a bit better with monophasic pills than with triphasics. Some women may experience spotting while trying to skip a period. If this occurs, continue taking the active pills until you finish the pack. Please be in touch with your provider if you have questions.

Do I need to stop taking the pill from time to time?

There is no evidence that taking a break from the pill is helpful to your body. We generally don't encourage stopping the pill unless you plan to be off for at least a few months. If you want to stop taking the pill, the best point to stop is at the end of a pack. Sometimes, your period can be delayed in returning after being on the pill.

Stopping the Pill:

The best way to stop the pill is at the end of a pack. Rarely one might want to stop the pill in the middle of a pack during the active pills. **IMPORTANT:** If stopping in the middle of a pack, it is recommended that one continues taking pills for 5 days AFTER the last coitus to maintain contraceptive protection in the body while any viable sperm could be present.

If normal menstruation doesn't return after 8 weeks, see your provider to determine why. Remember, you can become pregnant as soon as you stop taking the pills.

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In conclusion...

In 1965, Brown University was one of the first college campuses to prescribe oral contraceptives- the students involved were engaged to be married. Loud public outcry surrounded this decision. Today a prescription is readily available, sometimes the day you call for an appointment. The power to control one's reproduction or regulate one's menses remains a remarkable technology- Unfortunately, this is not easily available to women in other countries or even down the street from campus. Please don't hesitate to ask your provider any questions you have. We want you to feel confident and safe regarding the choices you make.

Monophasic Pill Diagram:



Triphasic Pills

