



Progestin-Only Pills

PATIENT EDUCATION SERIES

Progestin-only pills (POP's) are hormonal contraceptive pills which contain only progestin. Also, called the mini pill, POP's are useful for women who cannot or should not take estrogen. This includes women who are breast-feeding or who have worsened migraines or high blood pressure with combination contraceptive pills. Progestin-only pills are as effective as combination pills when taken at the same time every day, but there is a slightly higher failure rate of the POP if the woman is more than three hours late in taking it. A back-up method of birth control should be used for two days if a pill is forgotten or taken more than three hours late.

Progestin-only pills are taken on a 28-day cycle, and all 28 pills contain hormone. One pill should be taken every day at the same time, and there is no placebo pill week. Breakthrough bleeding or spotting can occur with progestin-only pills.

Only one progestin-only oral contraceptive (OC) formulation is marketed in the United States: norethindrone 0.35 mg tablets (Camila, Micronor, Nor-QD, and other generic versions). The progestin dose is substantially lower than the dose in any combination oral contraceptive. It is dispensed in packs of 28 active pills, which are taken continuously (ie, no pill-free or non-hormonal pill week).

How POP's work - Progestin-only pills work by suppressing ovulation, thickening cervical mucus, and thinning the endometrium. In contrast to oral estrogen-progestin contraceptive pills, ovulation is not consistently suppressed. Therefore, the effects of progestin-only OCs on cervical mucus and endometrium are the critical factors in prevention of conception. Within hours of administration, progestin-only OCs reduce the volume of cervical mucus and increase its viscosity, which prevents sperm from passing through the cervical canal and endometrial cavity. These changes persist for only 20 hours, which is why it is important to take the POP each day at the same time.

Efficacy - National survey data used to estimate hormonal contraceptive failure rates with typical use have not distinguished between users of combination OCs (8 percent failure rate in first year of use) and progestin-only OCs. Because the great majority of OCs used in the United States represent combination pills, and because the failure rate with progestin-only OCs is likely to be higher than with combination pills, the typical use failure rate with progestin-only OCs is likely to be higher than 8 percent.

How to start the mini pill

1. POP's should be initiated during the first five days of menses, and a back-up contraceptive be used for two days after starting POP's. Because of the short duration of action and the short half-life of progestin-only pills, it is essential that the pill be taken at the same time each day to maximize contraceptive efficacy. Once you choose a time to take the pill, you must take it within 3 hour of that target time.

2. A back-up contraceptive (eg, condoms) should be used for at least two days if a progestin-only pill is taken more than three hours late or forgotten on any given day. The patient should also resume taking daily progestin-only pills as soon as possible.

3. If you miss a pill during the 3-hour window, take it as soon as you remember, even if it means you will take 2 pills in one day. Use a backup method such as male condoms or abstain from vaginal sex during the next 48 hours. Take further pills at the usual time. If you vomit within 4 hours after taking a pill, or if you have diarrhea, your body might not properly absorb the medication in the pill. Keep taking the pills on schedule but use a backup method such as the male condom every time you have sex through 48 hours after the vomiting and diarrhea are over.

4. As you continue to take POP's, always start the next pack of POP's the day after the last pack is finished. Do not take any break or days off between backs. Plan to always have your next pack ready **before** you finish each pack.

5. If you are switching to the POP pill from a combined oral contraceptive (regular birth control pill) skip the 7 inactive pills at the end of the pack and start the progesterone only pill the day after the last active pill.

6. If you have already had intercourse without adequate protection because you missed pills consider the taking Plan B, and seek advice from your provider as needed.

7. Get a pregnancy test if you have not taken all your pills on time and had sex without a backup method. Do not stop taking the pills until you know the pregnancy test result. If your pregnancy test is positive stop taking the progesterone pill and consult your provider.

8. Changes in your menstrual periods are common in women using progesterone only pills (frequency,

length, and bleeding between periods). These changes are usually not dangerous. If you have unusual bleeding, keep taking the progesterone-only pill; if it lasts more than 8 days or is particularly heavy, consult your provider.

SIDE EFFECTS

Menstrual changes - As with all continuous progestin-only contraceptives, menstrual irregularities are common in progestin-only pill users and represent the most frequent cause for contraceptive discontinuation. Unscheduled bleeding, spotting, and amenorrhea are common menstrual patterns during progestin-only pill use, and may likely persist as the pill is disrupting the normal ovulatory hormone cycle.

Follicular cysts - Sonographic studies have shown that ovarian cysts are more common in progestin-only OC users than other women. While most ovarian cysts cause little or no symptoms and resolve without treatment, you should let your provider know if you experience onset of abdominal pain while taking the POP's.

Acne - Acne may sometimes flare, likely reflecting the androgenic nature of the progestin which stimulates the sebaceous glands. This response varies across individuals.

Weight gain - Weight gain is not a side effect of progestin-only pills.

Headache - Progestin-only OCs are less likely to cause headaches than other hormonal contraceptives.

Risks and benefits - Progestin-only contraception is an option for women in whom an estrogen-containing contraceptive is either contraindicated or causes additional health concerns. Progestin-only hormonal methods appear to be appropriate contraceptive choices for many women with contraindications to estrogen-containing contraceptives. Given the low dose of hormone, the failure rate of progestin-only OCs in highly fertile women is higher than that with other hormonal contraceptive methods. However, serious complications are less common than with combined estrogen-progestin contraceptives and the method is less invasive and more readily reversible than progestin injections, implants, and intrauterine contraception.

Effect on cardiovascular risk - Progestin-only OCs have little effect on coagulation factors, blood pressure or lipid levels. Large studies have not identified an increased risk of stroke, myocardial infarction, or venous thromboembolism with use of

progestin-only OCs. Thus, progestin-only OCs represent a reasonable contraceptive choice for women at high risk of, coronary artery disease, cerebrovascular disease, venous thromboembolic disease, hypertension, or other conditions in which use of contraceptive doses of estrogen are contraindicated.

Ectopic pregnancy risk - Progestin-only pills lower the overall risk of ectopic pregnancy, as well as intrauterine pregnancy, by preventing ovulation or conception. Since women taking progestin-only pills do not appear to have a higher absolute risk of ectopic pregnancy than women using no contraception, a history of ectopic pregnancy does not contraindicate progestin-only OC use. However, if pregnancy occurs, the likelihood that the pregnancy is ectopic is higher in progestin-only OC users than in noncontraceptors (5 versus 2 percent).

Effect on bone mineral density - The only study assessing skeletal health in progestin-only OC users was conducted in breast-feeding women. Although breast-feeding resulted in a reversible reduction in spinal bone mineral density in women using barrier contraception, the small amounts of hormone in the progestin-only OC protected against this loss.

Effect on cancer risk - Daily use of a progestin protects against development of endometrial cancer. There is little epidemiologic data on the effect of progestin-only OCs on cancer risk. Available data suggest that associations between POP use and reproductive cancers parallel known associations with combination OCs. In particular, breast cancer risk does not appear to be significantly different from that in nonusers.

Effect on sexually transmitted infections - Use of progestin-only OCs does not protect users from acquiring sexually transmitted infections. However, thickened cervical mucus may reduce the risk of ascending infection with development of pelvic inflammatory disease. Latex is advised for protection against STI's.