

Science Says

Progestin-only pills are safe, effective, and appropriate for over-the-counter use

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The Society of Family Planning, with critical leadership from Carmela Zuniga, MA, and colleagues, has developed this high-level summary as a resource for members and advocates. Please note this summary of existing evidence should not be read as clinical guidance.

Progestin-only pills (POPs) are a safe method of contraception.

- POPs are a type of oral contraceptive that contain only one hormone — progestin — to prevent pregnancy.¹ In the US, POP products either contain norethindrone¹ or drospirenone,² and a norgestrel product is under consideration by the US Food and Drug Administration (FDA) for over-the-counter availability.³ POPs containing other progestins, including desogestrel and levonorgestrel, are available in other countries.¹
- POPs are safe for most people to take, including those with contraindications to estrogen, such as individuals who are breastfeeding, over 35 years old and who smoke, or have certain health conditions like migraines with aura, blood clots, or heart disease.⁴
- Studies have shown a low prevalence of contraindications for POPs^{5,6} and the US Medical Eligibility Criteria for Contraceptive Use lists only one condition — current breast cancer — as an unacceptable health risk for POP use.⁷
- Research demonstrates that people can accurately self-screen for contraindications to POPs.^{5,8}

POPs are effective at preventing pregnancy.

- With perfect use, POPs are 99% effective and with typical use (which includes delayed or missed pills) they are 93% effective.⁹
 - Findings from a recent review of studies with data on rates of effectiveness and efficacy suggest that POPs may be more effective than currently believed. Currently, seven pregnancies are estimated to occur if 100 people took the pill for a year, yet the review estimates that only two pregnancies would occur with typical use.¹⁰
 - A review analyzing failure rates for norgestrel 0.075 mg — the POP currently under consideration by the FDA for over-the-counter use — found that 0 to 2.4 pregnancies would occur during typical use if 100 people took the pill for a year.¹¹
- Current guidelines state that POPs should be taken 24 hours after the previous pill, with only a strict three hour window before effectiveness is compromised.¹ However, there is very little clinical data supporting this strict timing of intake.¹² Studies have shown that for some formulations — such as norgestrel,¹³ desogestrel,¹⁴ and drospirenone¹⁵ — delays of longer than three hours in pill intake do not appear to impact contraceptive efficacy.

Side effects and acceptability of POPs.

- Bleeding changes are a common side effect of POP use^{1,16} and have been documented as a common reason for discontinuation in studies,¹⁷ but recent data on the experiences of POP users show that many find irregular bleeding acceptable or feel neutral about it.^{18,19}
 - A cross-sectional online survey with individuals (550 adult and 115 adolescents) who participated in a trial evaluating over-the-counter use of norgestrel 0.075 mg tablets found that 80% of participants felt the menstrual bleeding they experienced was acceptable or they were neutral about it.¹⁸ Additionally, 77% of participants who had used contraception in the month prior to the trial said their overall over-the-counter POP experience was similar to or better than their previous method.¹⁸ Overall, 83% reported likelihood of future over-the-counter POP use, with a greater likelihood among Latinx and Black participants and adults with public insurance, prior pregnancies, and some college compared to counterparts.²⁰
 - A study comprised of online focus group discussions with 36 previous or current POP users found that some participants did not experience any breakthrough bleeding and many felt neutral about their bleeding because it was infrequent or light. More than three-quarters of participants described their experience as positive because they experienced little or no side effects.¹⁹
 - Some POP users may experience a decrease in or cessation of menstrual bleeding, which may be desirable for individuals that experience heavy or painful periods, or who prefer less or no bleeding.¹⁶

Health care providers and the general public support over-the-counter access of POPs.

- The first application for an over-the-counter birth control pill was submitted to the FDA by HRA Pharma²¹ and the FDA Advisory Committee — comprised of scientific experts and members of the public²² — voted unanimously to make a POP available over the counter.²³
- Major medical organizations including the American College of Obstetricians and Gynecologists,²⁴ the American Medical Association,²⁵ the American Academy of Family Physicians,²⁶ and the Society for Adolescent Health and Medicine²⁷ support making POPs and other birth control formulations available over the counter.
- Adults and teens in the US are interested in using POPs over the counter.
 - A nationally representative online survey with 2,026 adult women at risk of unintended pregnancy and 513 female teens found that 39% of adults and 29% of teens would likely use an over-the-counter POP.²⁸
 - Adults and teens are willing to pay between \$10-20/month for an over-the-counter POP.^{20,28}

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