

FDA Approves First Nonprescription Daily Oral Contraceptive

Availability of Opill without a prescription may reduce barriers to contraception access.

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Today [July 13], the U.S. Food and Drug Administration approved Opill (norgestrel) tablet for nonprescription use to prevent pregnancy— the first daily oral contraceptive approved for use in the U.S. without a prescription.

Approval of this progestin-only oral contraceptive pill provides an option for consumers to purchase oral contraceptive medicine without a prescription at drug stores, convenience stores and grocery stores, as well as online.

The timeline for availability and price of this nonprescription product is determined by the manufacturer. Other approved formulations and dosages of other oral contraceptives will remain available by prescription only.

“Today’s approval marks the first time a nonprescription daily oral contraceptive will be an available option for millions of people in the United States,” said Patrizia Cavazzoni, M.D., director of the FDA’s Center for Drug Evaluation and Research. “When used as directed, daily oral contraception is safe and is expected to be more effective than currently available nonprescription contraceptive methods in preventing unintended pregnancy.”

Nonprescription availability of Opill may reduce barriers to access by allowing individuals to obtain an oral contraceptive without the need to first see a health care provider.

Almost half of the 6.1 million pregnancies in the U.S. each year are unintended. Unintended pregnancies have been linked to negative maternal and perinatal outcomes, including reduced likelihood of receiving early prenatal care and increased risk of preterm delivery, with associated adverse neonatal, developmental and child health outcomes. Availability of nonprescription Opill may help reduce the number of unintended pregnancies and their potential negative impacts.

The contraceptive efficacy of norgestrel was established with the original approval for prescription use in 1973. HRA Pharma [applied](#) to switch norgestrel from a prescription to an over-the-counter product.

For approval of a product for use in the nonprescription setting, the FDA requires that the [applicant demonstrate](#) that the product can be used by consumers safely and effectively, relying only on the nonprescription drug labeling without any assistance from a health care professional. Studies showed that consumer understanding of information on the Opill Drug Facts label was high overall and that a high proportion of consumers understood the label instructions, supporting their ability to properly use the drug when it is available as an over-the-counter product. When properly used, Opill is safe and effective.

Opill should be taken at the same time every day; adherence to daily use at the same time of day is important for the effectiveness of Opill. Using medications that interact with Opill can result in decreased efficacy of Opill or the other medication, or both, potentially resulting in unintended pregnancy.

The most common side effects of Opill include irregular bleeding, headaches, dizziness, nausea, increased appetite, abdominal pain, cramps or bloating.

Opill should not be used by those who have or have ever had breast cancer. Consumers who have any other form of cancer should ask a doctor before use. Opill also should not be used together with another hormonal birth control product such as another oral contraceptive tablet, a vaginal ring, a contraceptive patch, a contraceptive implant, a contraceptive injection or an IUD (intra-uterine device).

Use of Opill may be associated with changes in vaginal bleeding patterns, such as irregular spotting and prolonged bleeding. Consumers should inform a health care provider if they develop repeated vaginal bleeding after sex, or prolonged episodes of bleeding or amenorrhea (absence of menstrual period). Individuals who miss two periods (or have missed a single period and have missed doses of Opill) or suspect they may be pregnant should take a pregnancy test. Consumers should discontinue Opill if pregnancy is confirmed.

Opill is not for use as emergency contraception and does not prevent pregnancy after unprotected sex.

Oral contraceptives do not protect against transmission of HIV, AIDS and other sexually transmitted diseases such as chlamydia, genital herpes, genital warts, gonorrhea, hepatitis B and syphilis. Condoms should be used to prevent sexually transmitted diseases.

The FDA granted the approval to Laboratoire HRA Pharma, recently acquired by Perrigo Company plc.

This [news release](#) was published by the Food and Drug Administration on July 13, 2023.