

## Opill<sup>®</sup> (norgestrel) – New over-the-counter approval

- On July 13, 2023, the [FDA announced](#) the approval of Perrigo's over-the-counter (OTC) [Opill \(norgestrel\)](#), to prevent pregnancy.
  - [Norgestrel](#) 0.075 mg tablet was originally approved as a prescription daily oral contraceptive in 1973.
  - The prescription product was marketed under the brand name Ovrette<sup>®</sup> until 2005, when distribution was stopped by the company for marketing reasons, and not for reasons of safety or effectiveness.
  - Opill tablets are not for use as emergency contraception.
  - Opill does not protect against HIV/AIDS or other sexually transmitted diseases.
- Opill is the first daily oral contraceptive approved for use without a prescription. Norgestrel is a progestin-only oral contraceptive; it does not contain estrogen.
  - Other formulations and dosages of oral contraceptives will remain available by prescription only.
- In accordance with a process to change the status of a drug from prescription to nonprescription, Perrigo provided data demonstrating that the drug is safe and effective for use as directed in its proposed labeling. The manufacturer also showed that consumers can understand how to use the drug safely and effectively without the supervision of a healthcare professional.
- Opill should not be used:
  - If the person is allergic to this product or any of its ingredients, such as FD&C yellow No.5 (tartrazine)
  - If a person has or ever had breast cancer
  - If a person is already pregnant or think they may be pregnant
  - Together with another birth control pill, vaginal ring, patch, implant, injection, or an intra-uterine device (IUD)
  - As an emergency contraceptive (morning after pill). This product does not prevent pregnancy when used after unprotected sex
  - If the person is male.
- The recommended dosage of Opill is one tablet orally at the same time every day.
  - A patient should use a condom (or another barrier method) every time they have sex during the first 2 days of use (48 hours) after they start their first pack of this product, because it takes 2 days for this product to start working.
  - When a patient finishes the pack, they should start the next one the following day without a break.
  - Consult the package label for additional administration instructions.
- Perrigo plans to launch OTC Opill in early 2024. Opill will be packaged in a box containing 28 tablets.
  - Perrigo has not released pricing for the OTC Opill yet.