FDA Greenlights First Over-the-Counter Oral Birth Control

Norgestrel birth control tablets—marketed as Opill by Laboratoire HRA Pharma, which was acquired by Perrigo Company plc—recently received US Food and Drug Administration (FDA) approval for nonprescription use to prevent pregnancy, the agency announced in a statement. The progestin-only pills, which were first approved in 1973 for prescription use, will be available for over-the-counter purchase at drug and convenience stores as well as online starting in 2024, according to a release from the manufacturer.

The FDA’s approval for nonprescription use is based on studies showing that consumers can use the drug safely and effectively without a clinician’s guidance. With perfect use, studies have shown the drug is 98% effective—where perfect use means taking 1 tablet at the same time each day with no gaps between monthly packs, and using other forms of contraception, such as condoms, if the person misses or delays taking a dose by more than 3 hours.

Common adverse effects include irregular vaginal bleeding, nausea, headaches, dizziness, increased appetite, abdominal pain, cramps, and bloating. The drug should not be taken by people with or who have a history of breast cancer and is not approved for use alongside other methods of hormonal birth control. In addition, the tablets should not be used as emergency contraception to prevent pregnancy after unprotected sex.

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Note: Source references are available through embedded hyperlinks in the article text online.