COMMUNICATION

COM-2023-042

PLEASE Drug Information PharmPix Clinical Department

Drug Information:

Remember that medical literature is dynamic and is continuously changing as new scientific knowledge is developed. We exhort the frequent revision of treatment guidelines to assure that your recommendations are consistent with the most updated information.

It is our priority to offer high-quality services and support practices for health promotion and diseases prevention. If you have any questions or wish to have more information regarding this document, you can call us directly or view PharmPix communications online.

QUESTIONS

Call us at 787-522-5252, ext. 220

Access our recent communications at our providers' portal: https://www.pharmpix.com/provide rs/.



PharmPix is committed to the health and wellness of our members.

The clinical team wants to communicate the latest upto-date drug information requested.

Opill[™] the First OTC Oral Contraceptive

On July 13, 2023, the Food and Drug Administration (FDA) approved Opill[™] as a nonprescription oral contraceptive.

Approval and Drug Facts:

Opill[™] is the first daily oral contraceptive approved for use for all ages in the United States (U.S.) without a prescription. The approval was granted to Perrigo Company.

It is a progestin-only birth control pill containing 0.075mg of norgestrel. The OTC approval was based on several label comprehension studies which showed consumers could use Opill[™] correctly based on the label. When properly used, it is safe and effective.

Opill[™] should be taken at the same time every day for it to be effective. The most common side effects include irregular bleeding, headaches, dizziness, nausea, increased appetite, abdominal pain, cramps, or bloating. Opill[™] is not for use as emergency contraception and does not prevent pregnancy after unprotected sex.

Availability:

The OTC availability of norgestrel is expected to help reduce barriers to access by allowing individuals to obtain an oral contraceptive without the need to first see a healthcare provider.

Opill[™] will be available in-store and online at leading retailers across the U.S. early in the first quarter of 2024. No pricing information has been shared by the manufactured.

Pricing information is not yet available.



Additional information can be found at: http://www.opill.com

If you have any questions or wish to have more information regarding this document, you can call us at 787-522-5252, ext. 220. Our pharmacists will help you. In addition, know that you can access our recent communications at our providers' portal: https://www.pharmpix.com/providers/.

PharmPix Drug Information Communication Number COM-2023-042 July 2023





REFERENCES:

1. Center for Drug Evaluation and Research. Learn more about opill (0.075mg oral norgestrel tablet). U.S. Food and Drug Administration. https://www.fda.gov/drugs/postmarket-drug-safety-information-

patients-and-providers/opill-0075mg-oral-norgestrel-tablet-information#:~text=On%20July%2013%2C%20the.nonprescription%20oral%20birth%20control%20pill. *FDA approves first nonprescription daily oral contraceptive*. U.S. Food and Drug Administration. <u>https://www.fda.gov/news-events/press-announcements/fda-approves-first-nonprescription-daily-oral-contraceptive</u>

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