

Opill® Frequently Asked Questions

Will consumers know how to use Opill correctly in an OTC setting?

In a clinical study, participants were able to correctly use Opill and/or use a barrier method when having sex for the 2 days following a missed pill, without assistance from a healthcare provider, on 97% of days.¹

Additionally, 95% of study participants were ≥85% adherent to daily Opill dosing or followed label directions to use a barrier method when having sex for the 2 days following a missed pill.¹ The results of this study indicate that the [Drug Facts Label](#) guides people to use Opill correctly without involvement of a healthcare provider.

How is Opill dosed?

Opill is dosed once daily at the same 0.075 mg norgestrel dose.² To effectively prevent pregnancy, Opill should be taken at the same time every day and no later than 3 hours following the time of the previous day's dose.²

When can someone start taking Opill?

Individuals can start Opill on any day of the week or of their cycle. Even if individuals are switching from another oral contraceptive, vaginal ring, or patch, they can start taking Opill the day after they stop the other method.^{2,*}

Opill is effective 48 hours after taking the first pill, so individuals need to use a barrier method, such as a condom, during sex for the first 2 days (48 hours) after starting Opill to prevent pregnancy.²

Who should not use Opill?

Opill should not be used by people who³:

- Have or ever had breast cancer
- Have allergies to this product or any of its ingredients, such as the color additive FD&C yellow No. 5 (tartrazine)
- Are currently using another birth control pill, vaginal ring, patch, implant, injection, or IUD
- Are pregnant or think they may be pregnant
- Are male

Individuals should consult with a healthcare provider prior to starting Opill if they³:

- Currently have vaginal bleeding between periods and have not already consulted with a physician
- Have liver tumors or liver disease
- Have or ever had any cancer

For further information about using progestin-only contraception in these situations, please refer to the [US Centers for Disease Control and Prevention \(CDC\) Medical Eligibility Criteria](#).

Will Opill affect future fertility?

Opill does not delay an individual's ability to get pregnant once they choose to stop taking Opill.²

Can Opill be used by people under 18 years of age?

Yes, the FDA approved Opill for people of all reproductive ages.² [Major medical organizations](#), such as the American College of Obstetricians and Gynecologists⁴ and the American Medical Association,⁵ among others, support OTC access to oral birth control for all ages.

What advice should be given to someone in case of a delayed or missed dose of Opill?

If a tablet is delayed for less than 3 hours, 1 tablet of Opill should be taken immediately, and then the individual should go back to taking their tablet at their usual time the following day.²

If an individual is more than 3 hours late taking their tablet or misses taking their tablet on 1 or more days:

- They should take 1 tablet as soon as they remember, then go back to taking Opill at their usual time. This means an individual may take 2 tablets in 1 day.³
- They must use a condom (or another barrier method) every time they have sex during the 2 days (48 hours) after they restart Opill because it takes 2 days for Opill to start working again.³

The individual should take a pregnancy test or talk to their doctor if their period is late after missing any tablets in the last month.³ All information can be found in the Opill Consumer Information Leaflet that is included with each pack of Opill.



What drugs may interact with Opill?

The effectiveness of Opill may be reduced by hepatic enzyme–inducing drugs that treat certain disorders, such as²:

- Seizures (barbiturates, carbamazepine, oxcarbazepine, phenytoin, topiramate, primidone)
- Tuberculosis (rifampin, rifabutin)
- Pulmonary hypertension (bosentan)
- HIV/AIDS (efavirenz)

Additionally, St John’s Wort (or any herbal products containing hypericum perforatum) may interfere with the efficacy of Opill.²

If emergency contraception (morning–after pill) has been taken within the last 5 days:

- Opill should not be used for 5 days after using the emergency contraceptive ella®, which contains ulipristal acetate. This might reduce the ability of both Opill and ella to prevent pregnancy.²
- A condom (or another barrier method) should be used every time the individual has sex until their next period.²

What if an individual becomes pregnant while taking Opill?

Opill should not be used if an individual knows or suspects they are pregnant. Opill is a medication to prevent pregnancy.³

- If an individual is pregnant, they should stop taking Opill and seek appropriate medical care.³
- Exposure during pregnancy will not cause harm.⁶

What if an individual experiences migraines while taking Opill?

Opill is appropriate for use in people who have migraines, including those with migraine with aura.⁶ If an individual’s headaches become more frequent or severe, they should consult with a doctor for appropriate evaluation.³

What routine healthcare visits should still be scheduled?

There is no need for any screening prior to use of Opill or for routine visits to initiate or continue Opill.⁷ However, the Opill label encourages users to continue to get routine preventative healthcare screening.³

For specific recommendations, see the [Selected Practice Recommendations for Contraceptive Use, 2016](#).

Will Opill also be available as a prescription?

Opill does not require a prescription and can be purchased OTC. Opill can be accessed with a prescription and can be covered or reimbursed in the states where a prescription is required for insurance coverage/reimbursement.

Where will consumers be able to purchase Opill?

Opill is available OTC at most retailers nationwide and online at Opill.com, with subscription options available.

*Read all label information and use as directed.

ABBREVIATIONS

AIDS, acquired immunodeficiency syndrome; CDC, US Centers for Disease Control and Prevention; FD&C, Federal Food, Drug, and Cosmetic; FDA, US Food and Drug Administration; HIV, human immunodeficiency virus; IUD, intrauterine device; OTC, over the counter.

REFERENCES

1. Joint Meeting of the Nonprescription Drugs Advisory Committee and the Obstetrics, Reproductive, and Urologic Drugs Advisory Committee – Sponsor Briefing Document. Opill (norgestrel 0.075 mg tablets) for Rx-to-OTC switch. Available at: <https://www.fda.gov/media/167893/download>. Accessed August 4, 2023.
2. US Food and Drug Administration. Opill Consumer Information Leaflet. Available at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2023/017031s041lbl.pdf. Accessed January 31, 2024.
3. US Food and Drug Administration. Opill label. Available at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2023/017031s041lbl.pdf. Accessed November 3, 2023.
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6. Curtis KM, et al. U.S. Medical Eligibility Criteria for Contraceptive Use, 2016. *MMWR Recomm Rep.* 2016;65(3):1-104.
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