

Opill (0.075mg Oral Norgestrel Tablet) Information

[en Español \(/drugs/postmarket-drug-safety-information-patients-and-providers/informacion-sobre-opill-0075mg-tableta-oral-de-norgestrel\)](#).

Important Consumer information

When taking norgestrel nonprescription birth control tablets, it is very important to:

- Read the Drug Facts label and Consumer Information Leaflet before using the product, and re-read them every time you buy the product again.
- Take one tablet at the same time every day, even if you are having vaginal bleeding.
- Do not use the product if you have breast cancer, or ever had breast cancer in the past.
- Read the labeling about what to do if you miss a tablet.
- Talk to your health care provider if you have questions or concerns.

Background

On July 13, 2023, the FDA approved Opill as a nonprescription oral birth control pill.

Opill contains the hormone norgestrel and belongs to the class of medications known as progestins. Opill does not contain estrogen.

Questions and Answers

Q. Is norgestrel effective as a contraceptive?

The drug must be taken every single day and at the same time, or the effectiveness is reduced and pregnancy may occur.

With perfect use, norgestrel tablets are highly effective in preventing pregnancy. Based on the initial clinical trials of norgestrel tablets, the perfect-use effectiveness rate can be as high as 98%, meaning only 2 in 100 women will become pregnant in a year of use. Perfect use includes taking one tablet every day, and at the same time each day without any breaks between monthly packs. It also includes always using back-up birth control, like condoms, when the person misses or is delayed in taking the daily tablet for more than 3 hours. Perfect use is usually seen in clinical trials.

In real life, however, effectiveness of typical use of norgestrel tablets is lower than perfect use. Typical use takes into account human errors, such as forgetting to take the pill at the same time each day or not using a condom when the person misses a daily pill. The effectiveness of norgestrel tablet may be different for each person as some may find it difficult to use a product perfectly. In real world use, nonprescription norgestrel is expected to be less effective than prescription norgestrel used in clinical trials that led to its initial approval. However, nonprescription norgestrel contraception is very likely to be more effective than other currently available nonprescription contraceptive methods.

When taking oral nonprescription norgestrel, it is important to read the full Drug Facts label and Consumer Information Leaflet before using it, and to re-read all the labeling every time you buy the product again.

Q. Can you use oral norgestrel for reasons other than preventing unwanted pregnancy?

Nonprescription norgestrel is not approved in the U.S. for uses other than the prevention of pregnancy.

Q. How was norgestrel available prior to the approval of nonprescription norgestrel?

Norgestrel was approved for prescription use in the U.S. for prevention of pregnancy in 1973 but has not been available since 2005 because of the manufacturer's decision to stop selling the drug for business reasons.

Q. How is norgestrel available to consumers now?

Nonprescription norgestrel will be available to consumers in 2024 under the brand name Opill. FDA's approval of Opill as a nonprescription drug product provides an option for consumers to purchase this oral contraceptive medicine without a prescription at drug stores, convenience stores and grocery stores, as well as online. Please refer to the [manufacturer's website](https://opill.com/) (<https://opill.com/>). [↗](http://www.fda.gov/about-fda/website-policies/website-disclaimer) (<http://www.fda.gov/about-fda/website-policies/website-disclaimer>) for additional information on availability.

Q. Does norgestrel lose its effectiveness in women who are overweight or obese?

In general, some studies have suggested that hormonal contraceptives (not just norgestrel) might have somewhat reduced effectiveness for women who are overweight compared to women who are not overweight. At this time, the available data are not clear regarding whether hormonal contraceptives will have a higher pregnancy rate when used by women who are overweight or obese.

If you have concerns about the potential for reduced effectiveness of oral contraceptives based on your weight, discuss your concerns with your healthcare provider. They can provide personalized advice and help you choose the most appropriate contraceptive method based on your individual circumstances.

Q. Are there any side effects of norgestrel?

Like any medication, norgestrel can have side effects. Common side effects may include irregular vaginal bleeding, nausea, breast tenderness, and headaches. These side effects are generally mild and often resolve on their own. However, if you experience severe or persistent side effects, it is important to seek medical advice.

Q. Who should not use norgestrel?

Norgestrel should not be used:

- If you have or ever had breast cancer
- If you are already pregnant or think you may be pregnant
- Together with another birth control pill, vaginal ring, patch, implant, injection or an IUD (intra-uterine device)
- As an emergency contraceptive (morning after pill)
- If you are male

Q. What medications or supplements can interact with norgestrel?

Ask a healthcare provider or pharmacist before using norgestrel tablets if you:

- are taking a prescription drug for seizures, tuberculosis, HIV/AIDS, or pulmonary hypertension; or
- if you are taking a supplement containing St John's Wort (an herbal ingredient).

Norgestrel may interact with these drugs, or they may make norgestrel less effective in preventing pregnancy. Norgestrel may also interact with ulipristal acetate (an emergency contraceptive, or morning after pill).

Q. Can norgestrel protect against sexually transmitted infections (STIs)?

No, norgestrel does not protect against STIs. It is solely a contraceptive method and does not provide any protection against infections such as HIV/AIDS or gonorrhea. To prevent STIs, it is important to use barrier methods such as condoms in addition to oral contraceptives.

Q. What should I do if I miss a dose of norgestrel?

If you miss a dose of norgestrel, or if you have vomited after taking norgestrel, read the label for further instructions. The recommended course of action may involve taking the missed pill as soon as possible and continuing with the remaining pills as scheduled. To ensure pregnancy prevention with a missed dose, you should use backup contraception, such as condoms, for 48 hours after the missed dose or after vomiting.

Q. Is norgestrel safe for everyone to use?

Norgestrel is generally safe for most people who could get pregnant. However, **it should not be used for individuals with certain medical conditions, such as breast cancer, or those taking specific medications.** If there are questions about whether Opill is right for you, consult with a healthcare professional who can evaluate your medical history and guide you on the most appropriate contraceptive method for your individual needs.

Additional Resources

- [FDA News Release: FDA Approves First Nonprescription Daily Oral Contraceptive \(/news-events/press-announcements/fda-approves-first-nonprescription-daily-oral-contraceptive\)](#)
- [Office of Women's Health: Birth Control \(/consumers/free-publications-women/birth-control\)](#)
- [CDC: Contraception \(https://www.cdc.gov/reproductivehealth/contraception/index.htm\)](https://www.cdc.gov/reproductivehealth/contraception/index.htm)