

# STEPS

## New Drug Reviews

# Norgestrel 0.075 mg (Opill) for Contraception

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**Norgestrel 0.075 mg** (Opill) is a once-daily progestin-only oral contraceptive. It is labeled for use as an over-the-counter medication to reduce the likelihood of pregnancy.<sup>1</sup>

The terms woman and women may be used in this article to reflect original study populations of cisgender females, but the research may be extended to all people who could become pregnant.

### Safety

When used as directed, norgestrel is safe for most women with reproductive potential. It should not be used in people who have or have had breast cancer because norgestrel may stimulate breast cancer cell growth by activating the estrogen receptor.<sup>2</sup> It is unclear whether oral use of norgestrel for contraception can increase lifetime risk of breast cancer in women.<sup>3</sup> Norgestrel should not be used by women who have undiagnosed abnormal uterine bleeding or in women with benign or malignant liver tumors.<sup>4</sup>

Norgestrel should not be used during pregnancy, although inadvertent use in pregnancy has not been shown to harm a developing fetus.<sup>4</sup> The risk of ectopic pregnancy is higher in women taking norgestrel than in those not taking contraceptives.<sup>4</sup> Norgestrel is regarded as safe to take during breastfeeding, although small amounts of progestin may pass through breast milk.<sup>4</sup> Taking norgestrel increases the risk of symptomatic ovarian cysts, hepatic neoplasia, and liver dysfunction.<sup>4</sup>

There is a theoretical concern that hepatic enzyme-inducing medications, including St. John's wort, HIV medications (e.g., efavirenz), and certain antiepileptic medications, may decrease the effectiveness of norgestrel. If prescribing an enzyme inducer, physicians should ensure that patients use an alternative form of contraception concurrently.<sup>1</sup>

Drug	Dosage	Dose form	Cost of full course
Norgestrel (Opill)	0.075 mg orally once daily	0.075-mg tablet	Price not yet available

Norgestrel is not indicated for use as contraception in premenarchal women, postmenopausal women, or in men.<sup>1</sup>

### Tolerability

Up to 48% of patients may experience unscheduled uterine bleeding. Common adverse effects, including nausea, breast tenderness, and headaches, occur in 15% to 35% of patients taking norgestrel.<sup>5</sup> About 17% of patients will discontinue norgestrel due to adverse effects; about two-thirds of these patients report irregular bleeding as the cause for discontinuation.<sup>4</sup>

### Effectiveness

Daily norgestrel is effective in preventing pregnancy. Based on early studies, when norgestrel is used perfectly, the effectiveness rate is as high as 98% (i.e., 2 in 100 women will become pregnant over one year of use).<sup>6</sup> Perfect use includes taking one tablet daily, at the same time each day, and without any breaks between 28-day packs. Perfect use also includes using a backup birth control method, such as condoms, if a dose is missed or delayed by more than three hours after the usual scheduled dose. Typical use effectiveness is lower, estimated to be 91% to 93%. This rate is similar to that of prescription-only contraceptive pills (93%; both progestin-only and combined estrogen-progesterone pills). Norgestrel is significantly more effective than other nonprescription methods, which have a use effectiveness rate of 72% to 86%.<sup>7</sup> The data are insufficient regarding whether hormonal contraception is less effective in people who are overweight or obese.<sup>1</sup>

### Price

Although nonprescription norgestrel has been approved by the U.S. Food and Drug Administration, it is not yet available in pharmacies and prices are unknown. Currently, there is no requirement for insurance companies to reimburse the cost of this medication.

STEPS new drug reviews cover Safety, Tolerability, Effectiveness, Price, and Simplicity. Each independent review is provided by authors who have no financial association with the drug manufacturer.

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## Simplicity

Norgestrel is taken once daily. Each dose should be taken no more than three hours before or after the time the pill was taken on the previous day (i.e., between 21 and 27 hours after the previous dose).<sup>1</sup> If a dose of norgestrel is taken more than three hours late or is missed, another dose should be taken immediately, then normal once-daily dosing should be resumed. An alternative form of contraception, such as a condom, should be used during sexual intercourse for two days after a missed or delayed dose to prevent pregnancy.<sup>1</sup>

When switching from another birth control method to norgestrel, the first dose should be taken the day after the previous method is discontinued and an alternative form of contraception, such as a condom, should be used for the following two days to prevent pregnancy.<sup>1</sup>

## Bottom Line

Norgestrel is an effective contraceptive option in women who have contraindications to combined estrogen-progesterone treatment. Because norgestrel will be available without a prescription, it is a reasonable option for women unable to access a medical prescription for birth control. Patients who are taking norgestrel for contraception should be counseled about taking concurrent medications or supplements that may decrease its effectiveness.

Because norgestrel is an over-the-counter medication, its use may not be reflected in a patient's official health record. Physicians should ask their female patients of childbearing potential if they

are taking norgestrel for birth control before prescribing any agents that decrease its effectiveness, such as hepatic enzyme inducers.

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