

Prepare for Opill, the First OTC Oral Contraceptive

Norgestrel 0.075 mg tablets (*Opill*) will be the first daily oral contraceptive to make the Rx-to-OTC switch.

Rx norgestrel (*Ovrette*) was discontinued in 2005 for business reasons, not safety or efficacy concerns. Now it's back as OTC *Opill*.

The hope is to improve access to contraception...and limit the number of unintended pregnancies.

But it's too soon to say if cost or coverage will be a barrier.

Think of norgestrel as similar to Rx progestin-only pills...drospirenone (*Slynd*) and norethindrone (*Errin*, etc).

We're used to saving these for patients who can't take a combo OC, such as those who need to avoid estrogen (breastfeeding, migraine with aura, high risk of thrombosis, etc).

Continue to screen patients for contraindications to all OCs, such as breast cancer or severe liver problems.

Watch for interactions. For example, some CYP3A4 inducers (phenytoin, etc) can reduce the efficacy of any pill, patch, or ring.

Point out that progestin-only pills have a long safety track record...with fewer risks than combo OCs with estrogen.

On the other hand, caution that progestin-only pills are less forgiving than combo OCs if a dose is missed or taken late.

Explain that taking *Opill* at the same time daily is more effective than other OTC contraceptive options (condoms, spermicide, etc).

If patients opt for OTC norgestrel, ensure it's added to patient profiles...and reinforce proper use.

Opill will come in multiple 28-day pill pack options...likely in a 1-, 2-, 3-, or 6-month supply. Tell patients to take a pill at the same time every day...continuously with no breaks between packs.

Emphasize strict adherence...for the best efficacy. Suggest using tools (alarms, apps, etc) to ensure it's taken at the same time each day.

Recommend backup contraception for 2 days after starting the first pack...if a dose is more than 3 hours late...or if a patient vomits or has severe diarrhea within 4 hours of taking a dose.

Counsel patients that irregular menstrual bleeding is common with progestin-only pills...and to continue taking norgestrel if this happens.

Keep in mind, patients of any age or weight can purchase *Opill*. It's NOT an emergency contraceptive...and doesn't protect against STIs.

See our resource, *Choosing a Contraceptive*, for details about other options (IUDs, implants, etc), emergency contraceptives, and more.

Key References:

- FDA. Decisional Memorandum. New Drug Application 17031, Supplement 41, Application for Full Prescription-to-Nonprescription Switch of Norgestrel Tablets 0.075 mg. July 13, 2023.
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- Teal S, Edelman A. Contraception Selection, Effectiveness, and Adverse Effects: A Review. JAMA. 2021 Dec

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