



# Opill

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Pregnancy & Breastfeeding

**Brand Name:** Opill

**Generic Name:** norgestrel tablets

**Drug Class:** Contraceptives, Oral, Progestins

## What is Opill, and what is it used for?

Opill (0.075mg oral norgestrel) tablets are used by females of reproductive potential as a form of hormonal birth control available over the counter to prevent pregnancy. They are not for use as emergency contraception.

## Warnings

- There is a possibility of ectopic pregnancy in women who become pregnant or complain of lower abdominal pain while on Opill tablets.
- If follicular development occurs, atresia of the follicle is sometimes delayed, and the follicle may continue to grow beyond the size it would attain in a normal cycle. Generally these enlarged follicles disappear spontaneously. Often they are asymptomatic; in some cases they are associated with mild abdominal pain, and rarely they may twist or rupture, requiring surgical intervention.
- Irregular menstrual patterns are common among women using Opill Tablets. Undiagnosed abnormal uterine bleeding should be evaluated before Opill is prescribed.

- Discontinue Opill tablet use if jaundice or acute disturbances of liver function develop. Do not resume use until markers of liver function return to normal and Opill tablet causation has been excluded.
- The onset or exacerbation of migraine, or development of headache with a new pattern that is recurrent, persistent, or severe requires evaluation of the cause because women with migraine may be at increased risk of stroke.

## What are the side effects of Opill?

Serious side effects of Opill include:

- **Changes in menstrual bleeding.** You may have changes in menstrual bleeding, including bleeding and spotting between menstrual periods, or your menstrual periods may stop. Tell your healthcare provider if you have irregular or heavy bleeding, bleeding or spotting that goes on for a long time, spotting in between your periods, or if you have not had a menstrual period for 2 months after having normal periods.
- **Cysts on the ovary.** Some women using Opill develop a cyst on the ovary. These cysts are small sacs of fluid and usually disappear on their own, but sometimes they can cause pain. Sometimes surgery is needed to remove a cyst on the ovary.
- **Allergy. Opill contains FD&C Yellow No. 5 (tartrazine)** which may cause allergic-type reactions (including bronchial asthma) in certain susceptible persons. Although the overall incidence of FD&C Yellow No. 5 (tartrazine) sensitivity in the general population is low, it is frequently seen in patients who also have aspirin sensitivity.

## The most common side effects of Opill include:

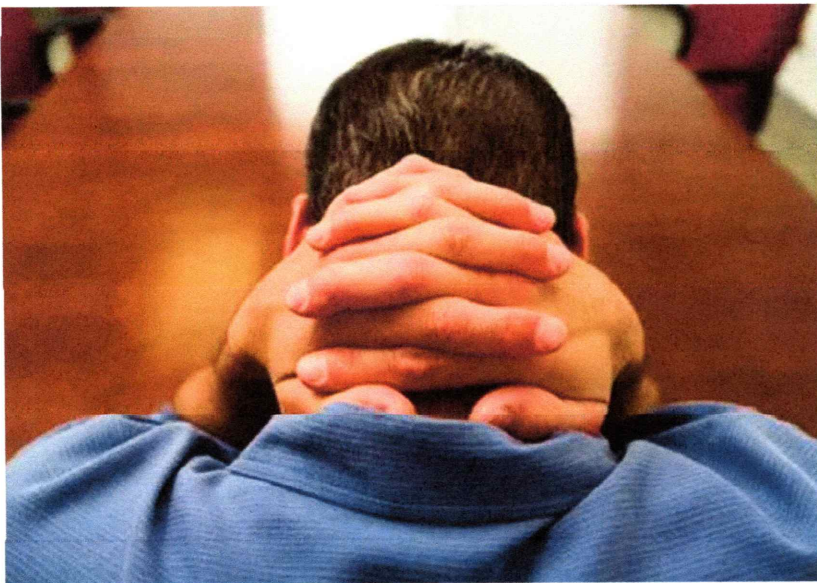
- headache,
- dizziness,
- nausea,
- increased appetite,
- abdominal pain, cramps and bloating,
- fatigue,
- vaginal discharge,

- dysmenorrhea,
- nervousness,
- backache,
- breast discomfort, and
- acne

These are not all the possible side effects of Opill. Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

### Call your healthcare provider right away if you:

- think you might be pregnant
- have sudden or severe pain in your belly (you could have an ectopic pregnancy)
- you repeatedly have vaginal bleeding that is brought on by sex
- have heavy vaginal bleeding or bleeding that concerns you
- start having migraines with aura (headaches that start with changes in vision) or your migraines get worse
- have jaundice, yellowing of your skin or whites of your eyes (especially with fever, tiredness, loss of appetite or dark colored urine)



### — SLIDESHOW —

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### What is the dosage for Opill?



Opill must be taken **at the same time every day**, so choose a time and then take the pill at that same time every day. If you take a pill late, and especially if you miss a pill, you are more likely to get pregnant.

### What are some important points to remember when taking Opill?

- You may have some bleeding between periods. Do not stop taking your pills if this happens. Bleeding between periods is usually temporary and does not mean there is a problem; however, if you repeatedly have vaginal bleeding that is brought on by sex or bleeding is prolonged (more than 8 days) or unusually heavy, consult your health-care provider.
- If you have not had a menstrual period for 2 months (or you have missed a single period but you have missed doses of Opill) after you have had regular periods or think you may be pregnant, you should have a pregnancy test.
- If you vomit within 4 hours after taking a pill, or have diarrhea, absorption may not be complete; therefore, use a nonhormonal back-up method of birth control (such as a condom or spermicide) every time you have sex during the next 48 hours.

If you are not sure about how to take Opill, ask your healthcare provider.

### When can I start Opill?

- You can start taking your first pill on any day, use a non hormonal back up method of birth control (such as a condom or spermicide) every time you have sex during the first 48 hours after starting Opill.
- Start the next pack the day after the last pack is finished. There is no break between packs. Always have your next pack of pills ready.
- If you have had a miscarriage or an abortion, you can start Opill the next day. In addition, you should use a non-hormonal back-up method of birth control for the first 48 hours.
- If you gave birth and are NOT breastfeeding, you can start Opill the next day. In addition, you should use a non-hormonal back-up method of birth control for the first 48 hours. If you are breastfeeding see section **“Is it safe to breastfeed while using Opill?”**

### What if I want to Switch Pills?

- If you are switching from the combined pills (containing both estrogen and progestogen) to Opill (progestin only), take the first Opill the day after you finish the last active combined pill. Do not take any of the inactive pills from the combined pill pack.

- If you switch to Opill tablets from another brand of POPs, you can start the new pack at any time.

### **What if I want to change from another type of progestin-only method (IMPLANT, INJECTION) or IUD?**

- Start taking Opill on the day of an implant or IUD removal or, if using an injection, the day the next injection would be due. In addition, use a non-hormonal back-up method of birth control for the first 48 hours after starting Opill tablets.

### **What if I am late or miss taking Opill?**

#### **If you are late taking a single pill:**

- **If you are less than 3 hours late** from your usual time you take the pill, take 1 pill immediately and go back to taking your pill at your usual time the following day.
- **If you are more than 3 hours late**
  - take 1 pill as soon as you remember and go back to taking your pill at your usual time. This means you may take 2 pills in 1 day.
  - you must use a condom (or another barrier method) every time you have sex during the 2 days (48 hours) after you restart Opill, because it takes 2 days to start working again.

#### **If you miss more than one pill:**

- Take the first missed pill as soon as you remember, even if it means you take 2 pills in 1 day. Then continue taking one pill daily at your usual time.
- You must use a condom (or another barrier method) every time you have sex during the 2 days (48 hours) after you restart Opill, because it takes 2 days to start working again.
- If you miss 3 or more pills, consider the possibility that you may be pregnant.
- If you are not sure what to do about the pills you have missed, keep taking Opill and use a condom (or another barrier method) every time you have sex until you can talk to your healthcare provider.

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## What drugs interact with Opill?

- The effectiveness of progestin only pills is reduced by hepatic enzyme inducing drugs such as phenytoin, carbamazepine, barbiturates, rifampin, efavirenz, bosentan and herbal preparations containing St. John's Wort (*hypericum perforatum*). This could result in unintended pregnancy or breakthrough bleeding.

During concomitant use of Opill and substances that may affect its efficacy, it is recommended that a nonhormonal back-up method of contraception (such as condom) be used in addition to the regular intake of Opill tablets. Use of a nonhormonal back-up method is recommended for 28 days after discontinuation of substances that have led to induction of hepatic microsomal enzymes. For women receiving long-term therapy with hepatic enzyme inducers, another method of contraception should be considered.

- Effectiveness of progestin-containing hormonal contraceptives and emergency contraceptive ulipristal acetate may be decreased if progestin-containing hormonal contraceptives are used within five days after ulipristal acetate dosing.

If a woman wishes to use Opill tablets after using ulipristal acetate, she should do so no sooner than 5 days after the intake of ulipristal acetate and she should use a reliable barrier method for subsequent acts of intercourse until her next menstrual period. Consult the product information of concomitant medications/substances to identify potential interactions.

## Gastrointestinal

Diarrhea and/or vomiting within 4 hours after taking a pill may reduce hormone absorption. Women should use of a nonhormonal back-up method of birth control (such as a condom or spermicide) during the next 48 hours.

## Interactions with Laboratory Tests



The following endocrine tests may be affected by Opill Tablets use:

- Sex hormone-binding globulin (SHBG) concentrations may be decreased.
- Total thyroxine concentrations may be decreased, due to a decrease in thyroid binding globulin (TBG). However, free thyroxine level should remain unchanged.

## FD &C Yellow No. 5

Opill Tablets contains FD&C Yellow No.5 (tartrazine) which may cause allergic-type reactions (including bronchial asthma) in certain susceptible persons. Although the overall incidence of FD&C Yellow No. 5 (tartrazine) sensitivity in the general population is low, it is frequently seen in patients who also have aspirin hypersensitivity.

## Carbohydrate and Lipid Effects

Some Opill Tablets users may experience slight changes in glucose tolerance with increases in plasma insulin, but women with diabetes mellitus who use progestin-only oral contraceptives do not generally experience changes in their insulin requirements.

Lipid metabolism is occasionally affected in that HDL1, HDL2, and apolipoprotein A-I and A-II may be decreased; hepatic lipase may be increased. There is usually no effect on total cholesterol, HDL3, LDL, or VLDL.

The effect of progestin-only oral contraceptives on carbohydrate and lipid metabolism is generally not clinically significant.

## Pregnancy and breastfeeding

- Opill tablets are contraindicated for use in pregnant women because there is no need for pregnancy prevention in a woman who is already pregnant. Published studies report no harmful effects on fetal development associated with long-term use of contraceptive doses of oral progestins in pregnant women.
- **Discontinue Opill tablets if pregnancy is confirmed.**
- Small amounts of progestin pass into the breast milk, resulting in steroid levels in infant plasma. No adverse effects have been reported on breastfeeding performance or infant health. The developmental and health benefits of breastfeeding should be considered along with the

mother's clinical need for Opill tablets and any potential adverse effects on the breastfed infant from Opill tablets or from the underlying maternal condition.

- The limited available data do not indicate a significant delay in the return of normal ovulation and fertility following discontinuation of progestin-only oral contraceptives.

## Summary

Opill (0.075mg oral norgestrel) tablets are used by females of reproductive potential as a form of hormonal birth control available over the counter to prevent pregnancy. They are not for use as emergency contraception. The most common side effects of Opill include headache, dizziness, nausea, increased appetite, abdominal pain, cramps and bloating, fatigue, vaginal discharge, dysmenorrhea, nervousness, backache, breast discomfort, and acne.

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