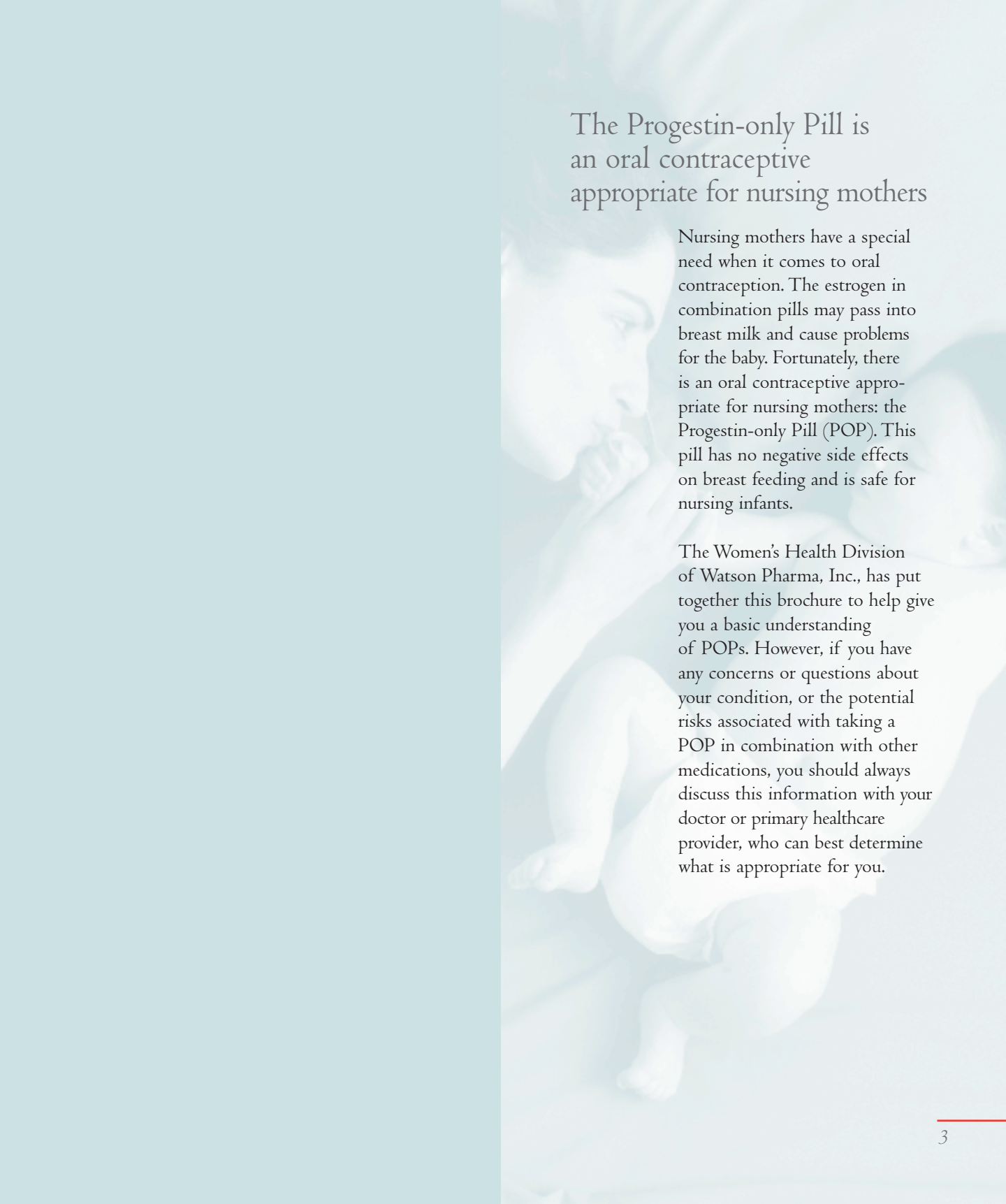


An Oral Contraceptive Choice for Nursing Mothers

Ask your healthcare
provider if NOR-QD[®]
(norethindrone tablets, USP)
is an appropriate choice
for you.



A soft-focus, light-colored photograph of a woman holding a baby. The woman is on the left, looking down at the baby. The baby is on the right, wearing a white diaper. The background is a light, textured surface. The overall tone is gentle and maternal.

The Progestin-only Pill is an oral contraceptive appropriate for nursing mothers

Nursing mothers have a special need when it comes to oral contraception. The estrogen in combination pills may pass into breast milk and cause problems for the baby. Fortunately, there is an oral contraceptive appropriate for nursing mothers: the Progestin-only Pill (POP). This pill has no negative side effects on breast feeding and is safe for nursing infants.

The Women's Health Division of Watson Pharma, Inc., has put together this brochure to help give you a basic understanding of POPs. However, if you have any concerns or questions about your condition, or the potential risks associated with taking a POP in combination with other medications, you should always discuss this information with your doctor or primary healthcare provider, who can best determine what is appropriate for you.

What is a POP and how does it work?

A POP is a birth control pill that contains only one hormone, progestin. The progestin in a POP is a synthetic version of progesterone, a sex hormone produced naturally in a woman's body. Progestin works by preventing a woman's ovaries from releasing eggs (ovulating) in approximately half of all users and by thickening the cervical mucus, which may prevent sperm from reaching the egg. Progestin may also slow the movement of the egg through the fallopian tubes. It may also prevent fertilized eggs from implanting in the uterus (womb).

What time of day should I take the pill?

You can decide what time of day would be most convenient for you, but it is very important that you take the pill at the same time every day. Every time that you take a pill late, you increase your chances of becoming pregnant.

What should I do if I forget to take a pill?

If you are more than three hours late or if you have missed a pill, take it as soon as you remember. Continue taking POPs at your regular time. You should use a backup method (such as a condom or foam) every time that you have sex for the next 48 hours.

If you have any question regarding a missed pill, continue taking POPs until you speak with your healthcare provider.



Can I start using POP when I start breastfeeding?

If you are exclusively breastfeeding (not supplementing with formula or food) you may start taking POPs six weeks after delivery. If you are partially breastfeeding (supplementing with formula or food) you may start taking POPs three weeks after delivery.

Can I take other medications while taking POP?

If you take some medications, including medication for seizures or tuberculosis, your pills may not work as well. You should inform your healthcare provider of all medications that you are taking before taking a POP.

Is spotting or bleeding between periods normal?

The most common side effect of POPs is a change in your menstrual bleeding. Your periods may either be early or late and spotting between periods is normal. Keep taking your pills and contact your healthcare provider with any concerns.



NOR-QD[®] (norethindrone tablets, USP): The Progestin-only Pill from Watson

NOR-QD is an appropriate oral contraceptive choice for nursing mothers as well as any women who cannot tolerate estrogen, such as women with high blood pressure or women who are at risk of developing blood clots. NOR-QD is manufactured by Watson Pharma, Inc., makers of an extensive line of high-quality, effective oral contraceptives.

What are the advantages of NOR-QD?

NOR-QD allows mothers to nurse their children and to have the protection of an oral contraceptive. As a progestin-only oral contraceptive, NOR-QD decreases many of the risks associated with oral contraceptives that contain estrogen.

But remember, NOR-QD helps prevent pregnancy. It does not protect a woman against HIV infection (AIDS) and other sexually transmitted diseases. If you have any additional questions, you should discuss them with your healthcare provider.

NOR-QD is easy to use

NOR-QD is taken once daily, every day. You can start taking it any day. There are no pill-free days or different-colored pills to consider. NOR-QD is compact enough to be carried in a purse and available in an easy-to-use 28-day format many women are familiar with.

Are there side effects with NOR-QD[®] (norethindrone tablets, USP)?

As with all oral contraceptives, there are some side effects. Most, however, are not serious. The incidence of menstrual irregularity, headache, breast tenderness, nausea, and dizziness may be increased among POP users. If any of the above symptoms continue, you should contact your healthcare provider.

Who should not take NOR-QD?

Progestin-only contraceptives should not be used by women who have a known or suspected pregnancy, known or suspected carcinoma of the breast, undiagnosed abnormal genital bleeding, benign or malignant liver tumors, or acute liver disease. POPs are not recommended if you take medication for epilepsy (seizures) or for tuberculosis. Also avoid taking POPs if you are allergic or hypersensitive to any of their components. Cigarette smoking greatly increases the possibility of suffering heart attacks and strokes. Oral contraceptives do not protect against HIV infection (AIDS) and other sexually transmitted diseases.

Please consult Patient Labeling in the package insert for complete details on NOR-QD.



NOR-QD[®]
(norethindrone tablets, USP)

Nor-QD[®] Tablets
(norethindrone 0.35 mg)

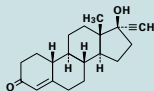
DETAILED INFORMATION FOR THE PATIENT

This product (like all oral contraceptives) is used to prevent pregnancy. It does not protect against HIV infection (AIDS) and other sexually transmitted diseases.

DESCRIPTION

Each yellow NOR-QD[®] tablet provides a continuous oral contraceptive regimen of 0.35 mg norethindrone daily, and the inactive ingredients include D&C Yellow No. 10, FD&C Yellow No. 6, lactose, magnesium stearate, povidone, and starch.

The chemical name for norethindrone is 17-Hydroxy-19-Nor-17^β-pregn-4-en-20-yn-3-one. The structural formula follows:



norethindrone

Therapeutic class = oral contraceptive.

INTRODUCTION

This leaflet is about birth control pills that contain one hormone, a progestin. Please read this leaflet before you begin to take your pills. It is meant to be used along with talking with your doctor or clinic.

Progestin-only pills are often called "POPs" or "the mini-pill." POPs have less progestin than the combined birth control pill (or "the pill") which contains both an estrogen and a progestin.

HOW EFFECTIVE ARE POPs?

About 1 in 200 POPs users will get pregnant in the first year if they all take POPs perfectly (that is, on time, every day). About 1 in 20 "typical" POPs users (including women who are late taking pills or miss pills) gets pregnant in the first year of use. The following table will help you compare the efficacy of different methods.

Table 1.
Comparison of reversible contraceptive methods: Percent of women who become pregnant during the first year of use.

Method	Percent of women experiencing a pregnancy within the first year of use	
	Average Use	Perfect Use
No contraception	85	85
Spermicides	21	6
Periodic abstinence	20	1-9 ¹
Withdrawal	19	4
Cervical caps		
Given birth	36	26
Never given birth	18	9
Diaphragms	18	6
Condoms		
Female	21	5
Male	12	3
Pills	3	
POPs		0.5
Combined pills		0.1
IUDs		
Progesterone	2	1.5
Copper T 380A	0.8	0.6
Injectables	0.3	0.3
Implant	0.09	0.09

Adapted with permission.²

1. Depending on method (calendar, ovulation, symptom-thermal, post-ovulation)
2. Hatcher RA, Trussell J, Stewart F, Stewart GK, Kowal D, Guest F, Cates W, Pollcar M. Contraceptive Technology 1994-1996. New York, NY: Irvington Publishers. 1994.

HOW DO POPs WORK?

- They make the cervical mucus at the entrance to the womb (the uterus) too thick for the sperm to get through to the egg.
- They prevent ovulation (release of the egg from the ovary) in about half the time.
- They also affect other hormones, the fallopian tubes and the lining of the uterus.

YOU SHOULD NOT TAKE POPs

- If there is any chance you may be pregnant.
- If you have breast cancer.
- If you have bleeding between your periods which has not been diagnosed.
- If you are taking certain drugs for epilepsy (seizures) or for TB. (See **USING POPs WITH OTHER MEDICINES** below.)
- If you are hypersensitive or allergic to any component of this product.
- If you have liver tumors, either benign or cancerous.
- If you have acute liver disease.

RISKS OF TAKING POPs

WARNING: If you have sudden or severe pain in your lower abdomen or stomach area, you may have an ectopic pregnancy or an ovarian cyst. If this happens, you should contact your doctor or clinic immediately.

1. Ectopic pregnancy. An ectopic pregnancy is a pregnancy outside the womb. Because POPs protect against pregnancy, the chance of having a pregnancy outside the womb is very low. If you do get pregnant while taking POPs, you have a slightly higher chance that the pregnancy will be ectopic than do users of some other birth control methods.

2. Ovarian cysts. These cysts are small sacs of fluid in the ovary. They are more common among POP users than among users of most other birth control methods. They usually disappear without treatment and rarely cause problems.

3. Cancer of the reproductive organs and breasts. Some studies in women who use combined oral contraceptives that contain both estrogen and a progestin have reported an increase in the risk of developing breast cancer, particularly at a younger age and apparently related to duration of use. There is insufficient data to determine whether the use of POPs similarly increases this risk.

Some studies have found an increase in the incidence of cancer of the cervix in women who use oral contraceptives. However, this finding may be related to factors other than the use of oral contraceptives and there is insufficient data to determine whether the use of POPs increases the risk of developing cancer of the cervix.

4. Liver tumors. In rare cases, combined oral contraceptives can cause benign but dangerous liver tumors. These benign liver tumors can rupture and cause fatal internal bleeding. In addition, a possible but not definite association has been found with combined oral contraceptives and liver cancers in studies in which a few women who developed these very rare cancers were found to have used combined oral contraceptives for long periods of time. There is insufficient data to determine whether POPs increase the risk of liver tumors.

SEXUALLY-TRANSMITTED DISEASES (STDs)

WARNING: POPs do not protect against getting or giving someone HIV (AIDS) or any other STD, such as chlamydia, gonorrhea, genital warts or herpes.

SIDE EFFECTS

1. Irregular bleeding. The most common side effect of POPs is a change in menstrual bleeding. Your periods may be either early or late, and you may have some spotting between periods. Taking pills late or missing pills can also result in some spotting or bleeding.

2. Other side effects. Less common side effects include headaches, tender breasts, nausea and dizziness. Weight gain, acne, and extra hair on your face and body have been reported, but are rare. If you are concerned about any of these side effects, check with your doctor or clinic.

USING POPs WITH OTHER MEDICINES

Before taking a POP, inform your health care provider of any other medication, including over-the-counter medicine, that you may be taking.

If you are taking medicines for seizures (epilepsy) or tuberculosis (TB), tell your doctor or clinic. These medicines can make POPs less effective:

- Medicines for seizures:
- Phenytoin (Dilantin[®])
 - Carbamazepine (Tegretol[®])
 - Phenobarbital

- Medicine for TB:
- Rifampin (Rifampicin)

Before you begin taking any new medicines be sure your doctor or clinic knows you are taking birth control pills that contain a progestin.

HOW TO TAKE POPs

IMPORTANT POINTS TO REMEMBER

- POPs must be taken at the same time every day, so choose a time and then take the pill at that same time every day. Every time you take a pill late, and especially if you miss a pill, you are more likely to get pregnant.
- 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.
- You may have some menstrual spotting between periods. Do not stop taking your pills if this happens.
- If you vomit soon after taking a pill, use a backup method (such as condom and/or spermicide) for 48 hours.
- If you want to stop taking POPs, you can do so at any time, but, if you remain sexually active and don't wish to become pregnant, be certain to use another birth control method.
- If you are not sure about how to take POPs, ask your doctor or clinic.

STARTING POPS

- It's best to take your first POP on the first day of your menstrual period.
- If you decide to take your first POP on another day, use a backup method (such as condom and/or spermicide) every time you have sex during the next 48 hours.
- If you have had a miscarriage or an abortion, you can start POPs the next day.

IF YOU ARE LATE OR MISS TAKING YOUR POPS

- If you are more than 3 hours late or you miss one or more POPS:
 1. TAKE a missed pill as soon as you remember that you missed it,
 2. THEN go back to taking POPs at your regular time,
 3. BUT be sure to use a backup method (such as condom and/or spermicide) every time you have sex for the next 48 hours.
- If you are not sure what to do about the pills you have missed, keep taking POPs and use a backup method until you can talk to your doctor or clinic.

IF YOU ARE BREASTFEEDING

- If you are fully breastfeeding (not giving your baby any food or formula), you may start your pills 6 weeks after delivery.
- If you are partially breastfeeding (giving your baby some food or formula), you should start taking pills by 3 weeks after delivery.

IF YOU ARE SWITCHING PILLS

- If you are switching from the combined pills to POPs, take the first POP the day after you finish the last active combined pill. Do not take any of the 7 inactive pills from the combined pill pack. You should know that many women have irregular periods after switching to POPs, but this is normal and to be expected.
- If you are switching from POPs to the combined pills, take the first active combined pill on the first day of your period, even if your POPs pack is not finished.
- If you switch to another brand of POPs, start the new brand anytime.
- If you are breastfeeding, you can switch to another method of birth control at any time, except do not switch to the combined pills until you stop breastfeeding or at least until 6 months after delivery.

PREGNANCY WHILE ON THE PILL

If you become pregnant, or think you might be, stop taking POPs and contact your physician. Even though research has shown that POPs do not cause harm to the unborn baby, it is always best not to take any drugs or medicines that you don't need when you are pregnant.

You should get a pregnancy test:

- If your period is late and you took one or more pills late or missed taking them and had sex without a backup method.
- Anytime you miss 2 periods in a row.

WILL POPS AFFECT YOUR ABILITY TO GET PREGNANT LATER?

If you want to become pregnant, simply stop taking POPs. POPs will not delay your ability to get pregnant.

BREASTFEEDING

If you are breastfeeding, POPs will not affect the quality or amount of your breastmilk or the health of your nursing baby.

OVERDOSE

No serious problems have been reported when many pills were taken by accident, even by a small child, so there is usually no reason to treat an overdose.

OTHER QUESTIONS OR CONCERNS

Cigarette smoking greatly increases the possibility of suffering heart attacks and strokes. Women who use oral contraceptives are strongly advised not to smoke.

Diabetic women taking POPs do not generally require changes in the amount of insulin they are taking. However, your physician may monitor you more closely under these conditions.

If you have any questions or concerns, check with your doctor or clinic. You can also ask for the more detailed "professional package labeling" written for doctors and other health care providers.

HOW TO STORE YOUR POPS

Store your POPs at room temperature 15°–25°C (59°–77°F).

Be certain to read new revisions of this leaflet. You may check the date of the most recent revision by phoning the manufacturer toll-free at 1-800-272-5525 or by writing to the address below.

Keep this and all medications out of the reach of children.

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Address medical inquiries to:
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Corona, CA 91720

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