Patients should be counseled that oral contraceptives do not protect against sexually transmitted diseases (STDs) such as Chlamydia, genital herpes, genital warts, gonorrhea, hepatitis B, and syphilis. Patients should be counseled that oral contraceptives do not protect against transmission of HIV (AIDS) and other sexually transmitted diseases (STDs/HIV).

1. General. This progestin-only oral contraceptive is indicated for the prevention of pregnancy in women who have elected not to use another method of contraception for their current method of contraception.10

2. Delayed follicular atresia/Ovarian cysts. If follicular development does not occur following ovulation, or if a cyst forms, they may feel tender or may result in severe abdominal pain.

3. Carbohydrate and lipid metabolism. Some studies suggest that oral contraceptive use has been associated with increased risk of serious cardiovascular disease in women younger than 50 years of age. However, these studies are not free of bias, and there is insufficient data to show whether the risk for developing cardiovascular disease is increased in women who use oral contraceptives.

4. Corticosteroids. Corticosteroids can reduce the effectiveness of herbal contraceptives. This could result in unintended pregnancy if herbal contraceptives are used as a contraceptive method. Therefore, it is important to inform patients about the potential risks associated with using herbal contraceptives.

5. Hepatic neoplasia. Some studies have suggested that oral contraceptive use has been associated with an increased risk of developing hepatic neoplasia in women older than 35 years of age. However, these studies are not free of bias, and there is insufficient data to show whether the risk for developing hepatic neoplasia is increased in women who use oral contraceptives.

6. Carcinogenesis. The limited available data indicate that oral contraceptives do not increase the risk of cancer in women of reproductive age.
DOSAGE AND ADMINISTRATION

To achieve maximum contraceptive effectiveness. Nor-QD must be taken exactly as directed. Oral contraceptives are never taken every day, at the same time. Administration is continuous, with no interruption between pill packs. See PAXIL LABELING for detailed instructions.

NEW SUPPLIED

Nor-QD (norethindrone) tablets are available in 28-tablet dispensers.

STORAGE

Store at controlled room temperature 20°-25°C (68°-77°F). See USP controlled room temperature.

DETAILS ABOUT THE INFORMATION

Patients should be counseled that oral contraceptives do not protect against transmission of HIV (AIDS) and other sexually transmitted diseases (STDs) such as Chlamydia, genital herpes, genital warts, gonorrhea, hepatitis B, and syphilis.

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.

PREVENTION-ONLY PILLS are often called "POPs" or "the mini-pills." These are low-dose progestin pills, without an estrogen. Two examples of use. There is insufficient data to determine whether the use of POPs similarly increases this risk.

Some studies have found an increase in incidence of cancer of the cervix in women who use contraceptive patches. However, the finding may be related to factors other than the use of estrogen and there is no evidence to show whether the use of POPs increases the risk of developing cancer of the cervix.

If you are pregnant. If you have been diagnosed with breast cancer.

 Patients should be counseled that oral contraceptives do not protect against transmission of HIV (AIDS) and other sexually transmitted diseases (STDs) such as Chlamydia, genital herpes, genital warts, gonorrhea, hepatitis B, and syphilis.

Some studies have found an increase in the incidence of cancer of the cervix in women who use contraceptive patches. However, the finding may be related to factors other than the use of estrogen and there is no evidence to show whether the use of POPs increases the risk of developing cancer of the cervix.

PATIENT INFORMATION

If you are taking certain drugs for epilepsy (seizures) or for TB. (See WARNINGS.)

You will not get a backup method until your doctor or clinic.

You will not get a backup method until your doctor or clinic.

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

How to store your Pops

Store your Pops at room temperature 68°-77°F (20°-25°C). This product's label may have been updated.

For current package insert and further product information, please visit www.actavis.com or call our medical communications department toll-free to 1-800-272-5525.

You only

Keep out of reach of children.

For all medical inquiries contact: Actavis Medical Communications

Parsippany, NJ 07054 USA

www.oralcontraceptives.com or call our medical communications department toll-free to 1-800-272-5525.

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