Levonorgestrel and Ethinyl Estradiol Tablets, USP
0.15 mg/0.03 mg

This drug should not be used by women with liver disease, varices, or varicose veins, women 35 years of age or older who smoke cigarettes, or women with a history of thromboembolic disease.

This is not a complete list. Ask your doctor about specific medical problems for which you may be more likely to develop side effects.

General information about oral contraceptives

Oral contraceptives, also known as birth control pills, are used to prevent pregnancy. They work by preventing ovulation, by thickening the cervical mucus, and by changing the endometrium so that fertilization and implantation of a fertilized egg cannot occur. If pregnancy does occur, the growth of the fertilized egg is prevented. These pills are also used to treat acne and to regulate menstrual cycles. Oral contraceptives are effective 99% of the time if they are taken as directed. They are used regularly at the same time each day. Oral contraceptives do not protect against sexually transmitted diseases, including HIV infection (AIDS) and other sexually transmitted diseases.

The percentage of women experiencing adverse events with oral contraceptive methods at any single dose level is shown in the following table. The percentages reported are based on the total number of women in the study at each dose level and may not reflect the percentage of women at each dose level who experienced adverse events.

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Other side effects that have been reported with oral contraceptives include:

- Difficulty in sleeping, weakness, lack of energy, fatigue, or change in mood.
- Nausea, vomiting, or abdominal discomfort.
- Breast tenderness, and difficulty wearing contact lenses.

In women, oral contraceptives may cause edema (fluid retention) with swelling of the face, hands, or ankles. In some women, itching of the skin and hair, and dryness of the skin may occur. In men, the skin may become dry and scaly. Hair loss may occur. In some cases, men may have an increase in the size of the breasts.

Other side effects that have been reported with oral contraceptives include:

- Amenorrhea or oligomenorrhea.
- Oligospermia.

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IMPORTANT POINTS TO REMEMBER

HOW TO TAKE THE PILL

1. Take the first “active” white to off-white pill of the first pack on the Sunday you start your first pack until the next Sunday (7 days):
   a. Sunday Starter: Start the next pack on the day after your last “reminder” pill. Do not use “active” white to off-white “active” pills in a row in any cycle in which you take drugs that can make oral contraceptives less effective.
   b. How to take the pills in the pill pack (WEEK 1 OR WEEK 2):
      1. Take one “active” white to off-white pill each day at the same time:
         - For the Sunday Starter:
         - You might be pregnant. If you have sex in the 7 days after you take the last “active” pill, your pill may not work as well. Use a back-up method anytime you have sex.
   c.HOW TO START THE PACK OF PILLS
      1. Before you start taking your pills:
         - You are not using contraception.
         - Stop taking your pills.
   d. Drug interactions
      1. Some drugs that you take may make birth control pills less effective.
         - Use a back-up method anytime you have sex.
   e. Back-up method
      1. ASH RECOMMENDATION: Use a back-up method anytime you have sex.
         - If you have any questions, please consult your healthcare provider.

A REMINDER FOR THOSE ON 28-DAY PACKS

2. You may not have your period this month but this is expected. However, if you stop your period earlier or it is irregular, consult your healthcare provider.
   a. If you stop your period earlier or it is irregular, consult your healthcare provider.
   b. If you start your period earlier or it is irregular, consult your healthcare provider.
   c. If you start your period earlier or it is irregular, consult your healthcare provider.

PREGNANCY TO PILL FAILURE

1. If you are breastfeeding, consult your doctor before starting oral contraceptives. If you are breastfeeding, you should not use oral contraceptives. If you are breastfeeding, you should not use oral contraceptives.
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