

WHITE FLINT PHARMACY
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Drug NDC: 50419-0403-03
Drug Name: SAFYRAL

What is this medicine?

DROSPIRENONE; ETHINYL ESTRADIOL; LEVOMEFOLATE (dro SPY re nown; ETH in il es tra DYE ole; lee voe ME FOE late) is an oral contraceptive (birth control pill). This medicine combines two types of female hormones, an estrogen and a progestin. This medicine also has levomefolate, a B vitamin. It is used to prevent ovulation and pregnancy. It is also used to treat the symptoms of premenstrual dysphoric disorder (PMDD), to treat acne, and to raise folate levels in women who want to use birth control.

This medicine may be used for other purposes; ask your health care provider or pharmacist if you have questions.

How should I use this medicine?

Take this medicine by mouth. To reduce nausea, this medicine may be taken with food. Follow the directions on the prescription label. Take this medicine at the same time each day and in the order directed on the package. Do not take your medicine more often than directed. A patient package insert for the product will be given with each prescription and refill. Read this sheet carefully each time. The sheet may change frequently. Talk to your pediatrician regarding the use of this medicine in children. Special care may be needed. This medicine has been used in female children who have started having menstrual periods.

Overdosage: If you think you have taken too much of this medicine contact a poison control center or emergency room at once. NOTE: This medicine is only for you. Do not share this medicine with others.

What should I tell my health care provider before I take this medicine?

They need to know if you have any of these conditions: abnormal vaginal bleeding; adrenal gland disease; blood vessel disease or blood clots; breast, cervical, endometrial, ovarian, liver, or uterine cancer; depression; diabetes; gallbladder disease; heart disease or recent heart attack; high blood pressure; high cholesterol; high potassium level; kidney disease; liver disease; migraine headaches; stroke; systemic lupus erythematosus (SLE); thyroid disease; tobacco smoker; an unusual or allergic reaction to estrogens, progestins, folates, or other medicines, foods, dyes, or preservatives; pregnant or trying to get pregnant; breast-feeding.

What if I miss a dose?

If you miss a dose, refer to the patient information sheet you received with your medicine for direction. If you miss more than one pill, this medicine may not be as effective and you may need to use another form of birth control.

Where should I keep my medicine?

Keep out of the reach of children. Store at room temperature between 15 and 30 degrees C (59 and 86 degrees F). Throw away any unused medicine after the expiration date.

NOTE: This sheet is a summary. It may not cover all possible information. If you have questions about this medicine, talk to your doctor, pharmacist, or health care provider.

What should I watch for while using this medicine?

Use an additional method of contraception during the first cycle that you take these tablets. If you have any reason to think you are pregnant, stop taking this medicine right away and contact your doctor or health care professional. Smoking increases the risk of getting a blood clot or having a stroke while you are taking birth control pills, especially if you are more than 35 years old. You are strongly advised not to smoke. This medicine can make your body retain fluid, making your fingers, hands, or ankles swell. Your blood pressure can go up. Contact your doctor or health care professional if you feel you are retaining fluid. This medicine may affect blood sugar levels. If you have diabetes, check with your doctor or health care professional before you change your diet or the dose of your diabetic medicine. This medicine can make you more sensitive to the sun. Keep out of the sun. If you cannot avoid being in the sun, wear protective clothing and use sunscreen. Do not use sun lamps or tanning beds/booths. If you wear contact lenses and notice visual changes, or if the lenses begin to feel uncomfortable, consult your eye care specialist. In some women, tenderness, swelling, or minor bleeding of the gums may occur. Notify your dentist if this happens. Brushing and flossing your teeth regularly may help limit this. See your dentist regularly and inform your dentist of the medicines you are taking. If you are going to have elective surgery, you may need to stop taking this medicine before the surgery. Consult your health care professional for advice. This medicine does not protect you against HIV infection (AIDS) or any other sexually transmitted diseases.

What side effects may I notice from receiving this medicine?

Side effects that you should report to your doctor or health care professional as soon as possible: allergic reactions like skin rash, itching or hives, swelling of the face, lips, or tongue; breast tissue changes or discharge; changes in vision; chest pain; confusion, trouble speaking or understanding; dark urine; general ill feeling or flu-like symptoms; light-colored stools; loss of appetite; nausea, vomiting; pain, swelling, warmth in the leg; right upper belly pain; severe headaches; shortness of breath; sudden numbness or weakness of the face, arm or leg; trouble walking, dizziness, loss of balance or coordination; unusual vaginal bleeding; yellowing of the eyes or skin. Side effects that usually do not require medical attention (report to your doctor or health care professional if they continue or are bothersome): acne; brown spots on the face; change in appetite; change in sex drive or performance; depressed mood; stomach cramps or bloating; unusually weak or tired; weight gain.

This list may not describe all possible side effects. Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.