Dienogest; Estradiol valerate oral tablets

MEDICATION GUIDE

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 is this medicine?

DIENOGEST; ESTRADIOL VALERATE is an oral contraceptive (birth control pill). This medicine combines two types of female hormones, an estrogen and a progestin. It is used to prevent ovulation and pregnancy. This medicine is also used to treat heavy menstruation (monthly periods) in women who also want to prevent pregnancy.

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. Follow the directions on the prescription label. You can take it with or without food. If it upsets your stomach, take it with food. 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 adolescents who have started having menstrual periods.

Overdosage: If you think you've taken too much of this medicine contact a poison control center or emergency room at once.

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.

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
- Blood vessel disease or blood clots
- Breast, cervical, endometrial, ovarian, liver, or uterine cancer
- Diabetes
- Gallbladder disease
- Heart disease or recent heart attack
- High blood pressure
- High cholesterol
- Kidney disease
- Liver disease or liver cancer
- Mental illness
- Migraine headaches
- Stroke
- Swelling of the face or tongue
- Systemic lupus erythematosus (SLE)
- Tobacco smoker
- An unusual or allergic reaction to estrogens, progestins, or other medicines, foods, dyes, or preservatives
- Pregnant or trying to get pregnant
- Breast-feeding

What may interact with this medicine?

- Antibiotics or medicines for infections, especially rifampin, rifabutin, rifapentine, griseofulvin, and possibly penicillins, tetracyclines, or macrolides like erythromycin
- Barbiturate medicines, such as phenobarbital
- Bosentan
- Carbamazepine
- Certain antidepressants
- Certain medicines for blood pressure like diltiazem, verapamil
- Certain medicines for fungal infections like ketoconazole and

NOTE: This medicine is only for you. Do not share this medicine with others.
itraconazole
• Cimetidine
• Felbamate
• Grapefruit juice
• Ketoconazole
• Lamotrigine
• Oxcarbazepine
• Phenytoin
• Ritonavir or other medicines for HIV infection or AIDS
• Soy isoflavones supplements
• St. John’s wort
• Topiramate
• Warfarin

This list may not describe all possible interactions. Give your health care provider a list of all the medicines, herbs, non-prescription drugs, or dietary supplements you use. Also tell them if you smoke, drink alcohol, or use illegal drugs. Some items may interact with your medicine.

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
• 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 these to your doctor or health care professional if they continue or are bothersome.]:
• Acne
• Brown spots on the face
• Change in appetite
• Change in sexual desire
• Depressed mood or mood swings
• Nausea
• Stomach cramps or bloating
• 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.

What should I watch for while using this medicine?

Visit your doctor or health care professional for regular checks on your progress. You will need a regular breast and pelvic exam and Pap smear while on this medicine.

If you have any reason to think you are pregnant, stop taking this medicine right away and contact your doctor or health care professional.

If you are taking this medicine for hormone related problems, it may take several cycles of use to see improvement in your condition.

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 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]
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.

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