## TITLE - DANAZOL / DANOCRINE LADOGAL MEDICATION PATIENT INFORMATION IN ENGLISH





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## **Danazol**

pronounced as (da' na zole)

#### **IMPORTANT WARNING:**

Danazol must not be taken by women who are pregnant or who could become pregnant. Danazol may harm the fetus. You will need to have a negative pregnancy test before you begin taking this medication. Start taking this medication during your menstrual cycle to be sure you are not pregnant. Use effective birth control during your treatment. Danazol may decrease the effectiveness of hormonal contraceptives (birth control pills, patches, rings, implants, or injections), so you should not use these as your only method of birth control during your treatment. You also must use a barrier method of birth control (device that blocks sperm from entering the uterus such as a condom or a diaphragm). Ask your doctor to help you choose a method of birth control that will work for you. If you become pregnant while taking danazol, call your doctor immediately.

Danazol can increase your risk that you will develop a blood clot in your arms, legs, lungs, heart, and brain that may cause a heart attack or stroke. Tell your doctor if you have or ever had a blood clot. If you experience any of the following symptoms call your doctor immediately: warm, red, swollen, or tender leg; trouble speaking or understanding; paralysis or numbness in face, arm or leg; sudden severe headache; sudden changes in vision, blurred or blackened vision, or seeing double.

Danazol may cause liver damage with abdominal bleeding in people who take danazol for a long time. Tell your doctor if you have or have ever had liver disease. If you experience any of the following symptoms call your doctor immediately: yellowing of the skin or eyes, pain in stomach area, extreme tiredness, or unusual bleeding or bruising.

Danazol can cause increased pressure of the fluid inside the skull. If you experience any of the following symptoms stop taking danazol and call your doctor immediately: headache, nausea, vomiting, or problems with your vision.

Keep all appointments with your doctor and the laboratory. Your doctor may order certain lab tests before and during your treatment to check your body's response to danazol.

Talk to your doctor about the risks of taking danazol.

## Why is this medication prescribed?

Danazol is used to treat endometriosis (a condition in which the type of tissue that lines the uterus [womb] grows in other areas of the body and causes infertility, pain before and during menstrual periods, pain during and after sexual activity, and heavy or irregular bleeding). Danazol is also used to treat fibrocystic breast disease (swollen, tender breasts with noncancerous lumps) when other treatments are not successful. Danazol is also used to prevent attacks in people with hereditary angioedema (inherited condition that causes episodes of swelling in the hands, feet, face, airway, or intestines). Danazol is in a class of medications called androgenic hormones. It works to treat endometriosis by shrinking the displaced tissue of the uterus. It works to treat fibrocystic breast disease by blocking the release of hormones that cause the breast pain and lumps. It works to treat hereditary angioedema by increasing the amount of a natural substance in the body.

#### How should this medicine be used?

Danazol comes as a capsule to take by mouth. It usually is taken twice a day for endometriosis or fibrocystic breast disease, or two or three times a day for hereditary angioedema. Follow the directions on your prescription label carefully, and ask your doctor or pharmacist to explain any part you do not understand. Take danazol exactly as directed. Do not take more or less of it or take it more often than prescribed by your doctor.

Do not stop taking danazol without talking to your doctor. If you have fibrocystic breast disease, breast pain and tenderness usually improve during the first month that you take danazol and go away after 2 to 3 months of treatment; breast lumps should improve after 4 to 6 months of treatment.

#### Other uses for this medicine

Danazol is also sometimes used to treat idiopathic thrombocytopenic purpura (ITP; an ongoing condition that may cause easy bruising or bleeding due to an abnormally low number of platelets in the blood). Talk to your doctor about the risks of using this medication for your condition.

This medication may be prescribed for other uses; ask your doctor or pharmacist for more information.

## What special precautions should I follow?

#### Before taking danzaol,

- tell your doctor and pharmacist if you are allergic to danazol, any other medications, or any of the ingredients in danazol capsules. Ask your pharmacist for a list of the ingredients.
- tell your doctor and pharmacist what prescription and nonprescription medications, vitamins, nutritional supplements, and herbal products you are taking or plan to take. Be sure to mention any of the following: anticoagulants ('blood thinners') such as warfarin (Coumadin, Jantoven), atorvastatin (Lipitor, in Caduet), carbamazepine (Carbatrol, Equetro, Tegretol, others), cyclosporine (Gengraf, Neoral, Sandimmune), medications for diabetes such as insulin, lovastatin (Altoprev), simvastatin (Zocor, in Vytorin), or tacrolimus (Astagraf, Prograf). Your doctor may need to change the doses of your medications or monitor you carefully for side effects.
- tell your doctor if you have porphyria (an inherited blood disease that may cause skin or nervous system problems); unexplained vaginal bleeding; cancer; or heart or kidney disease. Your doctor will

probably tell you not to take danazol.

- tell your doctor if you are breast-feeding. Do not breastfeed during your treatment with danazol.
- tell your doctor if you have or have ever had migraine headaches; epilepsy (seizures), diabetes; hypoparathyroidism (condition in which the body does not produce enough parathyroid hormone); high blood pressure; or any blood disorder.

## What should I do if I forget a dose?

Take the missed dose as soon as you remember it. However, if it is almost time for the next dose, skip the missed dose and continue your regular dosing schedule. Do not take a double dose to make up for a missed one.

#### What side effects can this medication cause?

## Danazol may cause side effects. Tell your doctor if any of these symptoms are severe or do not go away:

- acne
- · decrease in breast size
- weight gain
- · oily skin or hair
- flushing
- sweating
- vaginal dryness, burning, itching, or bleeding
- nervousness
- irritability
- absence of menstrual cycle, spotting, or change in menstrual cycle

# Some side effects can be serious. If you experience any of these symptoms or those listed in the IMPORTANT WARNING section, call your doctor immediately:

- deepening of voice, hoarseness, sore throat, increase in facial hair, baldness, or swelling of the arms or legs (in women)
- · red, peeling, or blistering skin

If you experience a serious side effect, you or your doctor may send a report to the Food and Drug Administration's (FDA) MedWatch Adverse Event Reporting program online (http://www.fda.gov/Safety/MedWatch [http://www.fda.gov/Safety/MedWatch]) or by phone (1-800-332-1088).

## What should I know about storage and disposal of this medication?

Keep this medication in the container it came in, tightly closed, and out of reach of children. Store it at room temperature and away from light and excess heat and moisture (not in the bathroom).

Unneeded medications should be disposed of in special ways to ensure that pets, children, and other people cannot consume them. However, you should not flush this medication down the toilet. Instead, the best way to dispose of your medication is through a medicine take-back program. Talk to your pharmacist or contact your local garbage/recycling department to learn about take-back programs in your community. See the FDA's Safe Disposal of Medicines website (http://goo.gl/c4Rm4p [http://goo.gl/c4Rm4p]) for more information if you do not have access to a take-back program.

It is important to keep all medication out of sight and reach of children as many containers (such as weekly pill minders and those for eye drops, creams, patches, and inhalers) are not child-resistant and young children can open them easily. To protect young children from poisoning, always lock safety caps and immediately place the medication in a safe location – one that is up and away and out of their sight and reach. http://www.upandaway.org [http://www.upandaway.org]

## In case of emergency/overdose

In case of overdose, call the poison control helpline at 1-800-222-1222. Information is also available online at https://www.poisonhelp.org/help [https://www.poisonhelp.org/help] . If the victim has collapsed, had a seizure, has trouble breathing, or can't be awakened, immediately call emergency services at 911.

### What other information should I know?

Before having any laboratory test, tell your doctor and the laboratory personnel that you are taking danazol.

Do not let anyone else take your medication. Ask your pharmacist any questions you have about refilling your prescription.

It is important for you to keep a written list of all of the prescription and nonprescription (over-the-counter) medicines you are taking, as well as any products such as vitamins, minerals, or other dietary supplements. You should bring this list with you each time you visit a doctor or if you are admitted to a hospital. It is also important information to carry with you in case of emergencies.

#### **Brand names**

• Danocrine ® ¶

¶ - This branded product is no longer on the market. Generic alternatives may be available.

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National Library of Medicine 8600 Rockville Pike, Bethesda, MD 20894 U.S. Department of Health and Human Services

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