**Patient & Caregiver Education**

**Danazol**

**Brand Names: Canada**
Cyclomen

**Warning**

- This drug may cause harm to the unborn baby if your child takes it during pregnancy.

- Do not let your child take this drug if she is pregnant. A pregnancy test will be done to show that your child is NOT pregnant before starting this drug.

- Birth control pills and other hormone-based birth control may not work as well to prevent pregnancy. Be sure your child uses some other kind of birth control also, like a condom, when taking this drug.

- If your child is pregnant or gets pregnant while taking this drug, call the doctor right away.

- Blood clots have happened with this drug. Sometimes, these blood clots have been deadly. Call the doctor right away if your child has chest, arm, back, neck, or jaw pain or pressure; coughing up blood; numbness or weakness on 1 side of the body, trouble speaking or thinking, change in balance, or change in eyesight; shortness of breath; or
swelling, warmth, or pain in a leg or arm.

- Severe liver problems have happened with long-term use of this drug. This could lead to life-threatening bleeding in the belly area. Follow how to give this drug as you were told by your child’s doctor. Do not give this drug to your child for longer than you were told.

- Raised pressure in the brain has happened with this drug. This can cause long lasting loss of eyesight and sometimes death. Call the doctor right away if your child has a bad headache, dizziness, upset stomach or throwing up, or seizures. Call the doctor right away if your child has a change in strength on 1 side that is greater than the other, trouble speaking or thinking, change in balance, or blurred eyesight or other change in eyesight.

What is this drug used for?

- It is used to treat swelling attacks in people with hereditary angioedema (HAE).

- It may be given to you for other reasons. Talk with the doctor.

What do I need to tell the doctor BEFORE my child takes this drug?

- If your child has an allergy to this drug or any part of this drug.

- If your child is allergic to any drugs like this one or any other drugs, foods, or other substances. Tell the doctor about the
allergy and what signs your child had, like rash; hives; itching; shortness of breath; wheezing; cough; swelling of face, lips, tongue, or throat; or any other signs.

- If your child has any of these health problems: An androgen-dependent tumor, genital cancer, heart disease, kidney disease, liver disease, or porphyria.

- If your child has blood clots or has had blood clots in the past.

- If your child has unexplained vaginal bleeding.

If your child is breast-feeding a baby:

- Be sure your child does not breast-feed a baby while taking this drug.

This is not a list of all drugs or health problems that interact with this drug.

Tell the doctor and pharmacist about all of your child’s drugs (prescription or OTC, natural products, vitamins) and health problems. You must check to make sure that it is safe for your child to take this drug with all of his/her drugs and health problems. Do not start, stop, or change the dose of any drug your child takes without checking with the doctor.

What are some things I need to know or do while my child takes this drug?

- Tell all of your child’s health care providers that your child is taking this drug. This includes your child’s doctors, nurses,
• If your child has high blood sugar (diabetes), you will need to watch his/her blood sugar closely.

• High cholesterol has happened with this drug. If you have questions, talk with the doctor.

• Have blood work checked as you have been told by the doctor. Talk with the doctor.

• This drug may affect certain lab tests. Tell all of your child’s health care providers and lab workers that your child takes this drug.

• This drug may affect how much of some other drugs are in the body. If your child is taking other drugs, talk with the doctor. Your child may need to have blood work checked more closely while taking this drug with other drugs.

• This drug may lower sperm counts in males. Talk with the doctor.

**If your child has menstrual periods:**

• Period (menstrual) changes have happened with this drug. This includes spotting, period timing changes, and periods that have stopped. Most of the time, these changes went back to normal within 60 to 90 days after stopping this drug. If your child’s period has stopped and does not go back to normal after she stops this drug, talk with your child’s doctor.
What are some side effects that I need to call my child’s doctor about right away?

**WARNING/CAUTION:** Even though it may be rare, some people may have very bad and sometimes deadly side effects when taking a drug. Tell your child’s doctor or get medical help right away if your child has any of the following signs or symptoms that may be related to a very bad side effect:

- Signs of an allergic reaction, like rash; hives; itching; red, swollen, blistered, or peeling skin with or without fever; wheezing; tightness in the chest or throat; trouble breathing, swallowing, or talking; unusual hoarseness; or swelling of the mouth, face, lips, tongue, or throat.
- Signs of liver problems like dark urine, feeling tired, not hungry, upset stomach or stomach pain, light-colored stools, throwing up, or yellow skin or eyes.
- Vaginal irritation.
- Change in breast size.
- This drug may cause your child to swell or keep fluid in his/her body. Tell your child’s doctor if he/she has swelling, weight gain, or trouble breathing after this drug is given.

If your child is or may be sexually active:

- Orgasm with less or no semen.

What are some other side effects of this drug?

All drugs may cause side effects. However, many people have no side effects or only have minor side effects. Call your child’s
doctor or get medical help if any of these side effects or any other side effects bother your child or do not go away:

- Flushing.
- Sweating a lot.
- Hair loss.
- Feeling nervous and excitable.
- Emotional ups and downs.
- Weight gain.
- Pimples (acne).
- For females, a deep voice, facial hair, pimples, or period changes.

These are not all of the side effects that may occur. If you have questions about side effects, call your child’s doctor. Call your child’s doctor for medical advice about side effects.

You may report side effects to your national health agency.

**How is this drug best given?**

Give this drug as ordered by your child’s doctor. Read all information given to you. Follow all instructions closely.

- To gain the most benefit, do not miss giving your child doses.
- Keep giving this drug to your child as you have been told by your child’s doctor or other health care provider, even if
your child feels well.

**What do I do if my child misses a dose?**

- Give a missed dose as soon as you think about it.
- If it is close to the time for your child’s next dose, skip the missed dose and go back to your child’s normal time.
- Do not give 2 doses at the same time or extra doses.

**How do I store and/or throw out this drug?**

- Store at room temperature.
- Protect from light.
- Store in a dry place. Do not store in a bathroom.
- Keep all drugs in a safe place. Keep all drugs out of the reach of children and pets.
- Throw away unused or expired drugs. Do not flush down a toilet or pour down a drain unless you are told to do so. Check with your pharmacist if you have questions about the best way to throw out drugs. There may be drug take-back programs in your area.

**General drug facts**

- If your child’s symptoms or health problems do not get better or if they become worse, call your child’s doctor.
- Do not share your child’s drug with others and do not give anyone else’s drug to your child.
- Keep a list of all your child’s drugs (prescription, natural
products, vitamins, OTC) with you. Give this list to your child’s doctor.

- Talk with your child’s doctor before giving your child any new drug, including prescription or OTC, natural products, or vitamins.
- Some drugs may have another patient information leaflet. If you have any questions about this drug, please talk with your doctor, nurse, pharmacist, or other health care provider.
- If you think there has been an overdose, call your poison control center or get medical care right away. Be ready to tell or show what was taken, how much, and when it happened.

**Consumer Information Use and Disclaimer**

This information should not be used to decide whether or not to take this medicine or any other medicine. Only the healthcare provider has the knowledge and training to decide which medicines are right for a specific patient. This information does not endorse any medicine as safe, effective, or approved for treating any patient or health condition. This is only a brief summary of general information about this medicine. It does NOT include all information about the possible uses, directions, warnings, precautions, interactions, adverse effects, or risks that may apply to this medicine. This information is not specific medical advice and does not replace information you receive from the healthcare provider. You must talk with the healthcare provider for complete
information about the risks and benefits of using this medicine.

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If you have any questions or concerns, talk with a member of your healthcare team. You can reach them Monday through Friday from 9:00 AM to 5:00 PM at _______________. After 5:00 PM, during the weekend, and on holidays, please call____________________. If there’s no number listed, or you’re not sure, call 212-639-2000.

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