PACKAGE LEAFLET
Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet:
1. What Danazol is and what it is used for
2. What you need to know before you take Danazol
3. How to take Danazol
4. Possible side effects
5. How to store Danazol
6. Contents of the pack and other information

1. What Danazol is and what it is used for

Danazol belongs to a group of medicines called antigonadotropins. Danazol lowers the amount of some hormones (gonadotrophins) in your body. It is used to treat:
- endometriosis (where the tissue that normally lines your womb and is shed during your period grows outside your womb). You may also be given Danazol before or after surgery for endometriosis.
- painful or heavy periods (menorrhagia)
- painful breast disease, but not malignant. This may be connected with your periods or caused by cysts (lumps) in the breast. Danazol is used where other treatments have not worked or when they cannot be taken.
- enlarged breasts (in both men and women).

2. What you need to know before you take Danazol

Do not take Danazol if you:
- are allergic to danazol or any of the other ingredients of this medicine (listed in section 6). Signs of an allergic reaction include: a rash, swallowing or breathing problems, swelling of your lips, face, throat or tongue.
- you have a rare inherited illness which affects your metabolism (called ‘porphyria’)
- are pregnant, might become pregnant or think you may be pregnant or are breastfeeding (see section ‘Pregnancy and breast-feeding’)
- have severe kidney, liver or heart disease
- or a member of your family have porphyria (a disorder of metabolism)
- have blood clots in your circulation or have a history of such events (thromboembolic disease)
- have a type of tumour (called an androgen dependent tumour) that is affected by steroids
- have unexpected bleeding from your vagina which has not been checked by a doctor.
- you are taking cholesterol lowering medicine (Simvastatin)
Do not take this medicine if any of the above apply to you. If you are not sure, talk to your doctor or pharmacist before taking Danazol.

Warnings and precautions

If any of the following conditions applies to you, or if you have had any of them in the past, you must talk to your doctor or pharmacist before taking Danazol.

- if you have taken Danazol or a similar medicine before and had side effects such as water retention, voice changes, growth of facial hair or muscle development
- if you have any liver or kidney problems
- if you have high blood pressure or heart disease
- if you have diabetes mellitus (high blood sugar)
- if you have a blood problem with increased amount of red blood cells, where the blood gets thicker (polycythaemia)
- if you have fits (epilepsy)
- if you have problems with fat metabolism (lipid disorders)
- if you have a history of blood clots
- if you get migraines
- if you are having treatment to remove a tumour
- if you may have breast cancer
- if you have an illness which could be made worse by fluid retention

Children and adolescents

Danazol should not be given to children and adolescents.

Elderly patients

Danazol should not be given to the elderly.

Other medicines and Danazol

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

In particular, tell your doctor if you are taking any of the following:

- steroids such as testosterone, oestrogen, progesterone (including ‘the pill’ or hormone replacement therapy – known as HRT)
- Statins such as simvastatin, atorvastatin and lovastatin. Danazol may increase the risk of muscle weakness or rapid breakdown of muscle.

Danazol may increase the effect of the following medicines:

- medicine to treat epilepsy, fits or convulsions such as carbamazepine, phenytoin, phenobarbital (anti-convulsants)
- anticoagulants such as warfarin (to thin the blood) as your dosage will need to be adjusted
- anaesthetics (see ‘Operations or tests’ section below)
- medicines used to prevent rejection of organ transplants such as ciclosporin, tacrolimus. Danazol can increase the levels of these medicines in your blood and may damage your kidneys.
- alpha calcidol (a form of vitamin D) used for vitamin D deficiency and illnesses where there is not enough calcium in the blood.

Danazol may lower the effect of the following medicines:
- anti-diabetic medication including insulin
- medicines used to lower blood pressure (anti-hypertensives)
- medicines for migraine

**Operations or tests**
If you are due to have an operation, tell your doctor you are taking Danazol. This is because Danazol can increase the effect of some anaesthetics.

If you are having tests, tell your doctor. This is because Danazol treatment may interfere with laboratory tests of male sex hormone (testosterone), fats (lipids), sugars and plasma proteins.

If you have to take Danazol for more than six months your doctor will arrange for an ultrasound test to check your liver.

Your doctor may take regular blood samples to check your blood and to check that your liver and thyroid are working properly.

If you are going to have a blood test, it is important to tell your doctor you are taking Danazol.

**Danazol with alcohol**

Do not drink alcohol during treatment. This is because drinking alcohol whilst taking Danazol can make you feel sick or short of breath.

**Pregnancy and breast-feeding**

Do not take Danazol if you are pregnant, think you may be pregnant or are planning to have a baby. Danazol may harm your unborn child. If you are of child-bearing age you must use reliable contraception during treatment, but not the contraceptive pill. If you think you may have become pregnant, stop taking Danazol immediately and tell your doctor.

Do not take Danazol if you are breast-feeding. Danazol may reach your baby through the breast milk. If you are planning to breastfeed, talk to your doctor or pharmacist.

Ask your doctor or pharmacist for advice before taking any medicine if you are pregnant or breast-feeding.

**Driving and using machines**

Danazol is not known to affect your ability to drive or use machines. However, some side effects such as dizziness, a spinning feeling, and changes in eyesight may occasionally occur. If affected, you should not drive or use machines.

**Danazol contains lactose.** If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.

3. **How to take Danazol**

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

Take this medicine by mouth.
Swallow Danazol capsules whole with a glass of water.
Before starting your course of treatment, your doctor will check if you are pregnant. If you are of child bearing age, you should start treatment on the first day of your period to avoid exposing a pregnancy to its possible effects. Use reliable contraception (such as an Intra Uterine Device or barrier method in
conjunction with contraceptive foam or jelly). The contraceptive pill should **not** be used until your treatment with Danazol has finished.

You must take Danazol as a continuous course. Your doctor may adjust your dose according to your response. Once your condition has improved, they may advise you to take a lower dose. If you feel the effect of your medicine is too weak or too strong, do not change the dose yourself, but ask your doctor.

**Adults:** The recommended dose is 200 mg to 800 mg each day in up to four divided doses. DO NOT TAKE more than 8 of the 100 mg capsules or 4 of the 200 mg capsules in one day. Your dose will depend on your needs and medical condition:

**Endometriosis:** the recommended dose is 200 mg to 800 mg daily for three to six months. Normally you will need to take Danazol for 6 months, but you may have to take it for up to 9 months. If your endometriosis is severe, or if your bleeding continues after 2 months of treatment, your doctor may give you a higher dose. Before an operation for endometriosis, the recommended dose is 400 mg to 800 mg daily for 3 to 6 weeks.

**Menorrhagia:** the recommended dose is 200 mg daily for 3 months.

**Breast disease:** the recommended dose is 200 mg to 300 mg daily for 3 to 6 months. To treat breast cysts the usual dose is 300 mg daily for 3 to 6 months.

**Enlarged breasts:** the recommended dose is 400 mg daily for 6 months. If you are a young adult, the starting dose may be 200 mg daily. If your condition does not improve in the first two months, your doctor may increase the dose to 400 mg daily.

**If you take more Danazol than you should**

If you accidentally take too many capsules, contact your doctor or nearest hospital emergency department immediately for advice. Take the medicine pack with you. This is so the doctor knows what you have taken.

**If you forget to take Danazol**

Unless it is nearly time for your next dose, take it as soon as you remember. Do not take a double dose to make up for a forgotten dose.

**If you stop taking Danazol**

Do **not** stop or change your treatment before talking to your doctor. Do not stop taking Danazol just because you feel better. If you stop, your illness may get worse.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

### 4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

**If any of the following happen, stop taking Danazol and tell your doctor immediately or go to your nearest hospital emergency department:**

- allergic reactions which may include signs such as skin rash, sudden swelling of the face, lips, tongue and/or throat which may cause difficulty breathing or swallowing
- skin rashes, which may be severe and occur with fever and/or swelling of the face
- an increase in the pressure of the fluid which surrounds the brain which can lead to changes in eye sight such as blurred vision
- numbness or weakness of the face or limbs, these may be signs of a stroke
- numbness/pain in the arms or legs, which may be caused by a blood clot
- pain or tightness in the chest, jaw or arm, these may be signs of a heart attack
- a reduction in the number of white blood cells which help fight infection. This may be seen in blood tests or you may notice an increase in the number of infections such as sore throat, mouth ulcers and fever that you get
- voice changes such as hoarseness or a sore throat, growth of facial or body hair, muscle development, or enlarged clitoris (part of the female sex organs)
- liver problems which may cause yellowing of your skin or whites of the eyes, dark urine, pale stools (jaundice), non-cancerous and cancerous tumours and blood-filled cysts in the liver
- liver injury that may cause pain in the liver or liver failure that may cause a swollen abdomen, mental disorientation and confusion
- blood-filled cysts in the spleen, which may rupture and cause bleeding
- an inflamed pancreas causing abdominal pain with sickness
- fits (epilepsy) may get worse if you suffer from fits, or you may develop epilepsy if you are prone to developing the condition.

These are serious side effects. You may need medical attention.

**Other side effects include:**
- weight gain, acne or greasy skin, hair loss (similar to male baldness)
- visual disturbances which may take the form of blurring or difficulty in focusing and in wearing contact lenses
- menstrual changes such as irregular periods, spotting or loss of periods. Your periods will usually return to normal 60 to 90 days after treatment, but sometimes you may have persistent loss of periods
- you may also have flushing, vaginal dryness or irritation, reduction in breast size and, in men, lowering of sperm count during treatment
- dizziness, a spinning feeling (vertigo)
- headaches which may be severe (migraine)
- feeling sick (nausea)
- changes in skin colour (pigmentation), flaking, peeling, red skin, unusual bruising or bleeding under the skin which may be seen as purple spots
- back ache, pain in the arms and legs, severe muscle cramps, muscle tremors or twitches, muscle or joint pain or swelling
- racing or irregular heart beat
- high blood pressure or if you already have had a high blood pressure condition, it may get worse
- if you are diabetic, your blood sugar levels may be affected. Even if you are not diabetic you may get low blood sugar
- feeling tired, mood changes
- changes in sex drive (libido)
- increased appetite, anxiety, nervousness, depression
- breathlessness, swelling or inflammation of the lungs (interstitial pneumonitis)
- chest or stomach pain
- water retention or bloating, which may occasionally lead to a feeling of tingling or numbness in the hands, sometimes known as carpal tunnel syndrome.

**Rare side effects:**
- sensitivity of the skin to sunlight.
Some rare side effects that may occur if Danazol is taken for a long time: if you have hereditary angioedema (an inherited condition causing swelling of the skin, lungs and digestive system) you may get blood in your urine.

Changes in blood tests
During treatment with Danazol, if you have blood tests, your doctor may notice:
- changes in the number of red blood cells or platelets in your blood. You may also notice that you bruise or bleed easily or unexpectedly
- an increase in certain types of white blood cells
- raised levels of an enzyme (creatine phosphokinase), which may be an indicator of muscle damage
- changes in the level of fat (lipid) in your blood
- an increase in liver enzymes (which are used to check how the liver is working)

Danazol may also affect the results of certain tests for thyroid function and specific tests which show activity relating to the production of red blood cells.

These changes do not usually cause symptoms and return to normal when you stop taking Danazol.

Reporting side effects
If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any side effects not listed in this leaflet.
You can also report side effects directly via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Danazol

Keep this medicine out of the sight and reach of children.

Store below 25°C.

Blister packs: Store in the original package in order to protect from light and moisture.

Containers: Keep the container tightly closed in order to protect from light and moisture.

Do not use this medicine after the expiry date which is stated on the carton after EXP. The expiry date refers to the last day of that month.

Do not use this medicine if you notice Danazol capsules look damaged in any way.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Danazol contains

The active substance is danazol. Each 100 mg capsule contains 100 mg danazol. Each 200 mg capsule contains 200 mg danazol.

The other ingredients are: lactose monohydrate (see section 2 “Danazol contains lactose”), cellulose microcrystalline, silica colloidal anhydrous, povidone K30, lactose anhydrous, sodium starch glycolate, sodium laurilsulfate and magnesium stearate. Capsule shell contains: gelatin, titanium
dioxide (E171); and for 100 mg only: iron oxide black (E172); and for 200 mg only: iron oxide red (E172), iron oxide yellow (E172), erythrosine (E127).

What Danazol looks like and the contents of the pack

Danazol capsules 100 mg are capsules with a light grey body and a dark grey cap marked in black “DL 100” and “G”

Danazol capsules 200 mg are capsules with a white body and an orange cap marked in black “DL 200” and “G”

Danazol Capsules are available in either:
- polypropylene containers with polyethylene caps
- plastic/aluminium foil blister strips
- HDPE containers with polyethylene snap closures.

Pack sizes of 28, 30, 50, 56, 60, 84, 90, 100, 112 and 250 capsules are available in all pack types. Not all pack sizes may be marketed.

Marketing Authorisation Holder

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