

PACKAGE LEAFLET: INFORMATION FOR THE USER

Danol 100mg Capsules **Danol 200mg Capsules** (danazol)

Is this leaflet hard to see or read?
Phone 0800 035 2525 for help

Read all of this leaflet carefully before you start taking this medicine

- 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. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects get serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

In this leaflet:

1. What Danol is and what it is used for
2. Before you take Danol
3. How to take Danol
4. Possible side effects
5. How to store Danol
6. Further Information

1. What Danol is and what it is used for

Danol contains a medicine called danazol. It works by changing the way some hormones act in your body. It is used to treat:

- Endometriosis – an illness where some of the tissues that line the womb are found elsewhere in the body. One way of treating this is to have an operation and to take Danol as well. Danol can also be used on its own, where other treatments have not worked
- Breast cysts (lumps) which may be painful, but not malignant. Danol is used where other treatments have not worked or when they cannot be taken.

2. Before you take Danol

Do not take this medicine and tell your doctor if:

- You are allergic (hypersensitive) to danazol or any of the other ingredients of Danol (listed in Section 6 Further Information). 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’)
- You are pregnant, might become pregnant, or think you may be pregnant.
- You are breast-feeding
- You have severe kidney, liver or heart disease
- You have ever had blood clots (thrombosis)
- You have a type of cancer which is affected by hormones

- You have unusual vaginal bleeding which has not been checked by a doctor
- You are taking cholesterol lowering medicine (Simvastatin)

Do not take if any of the above apply to you. If you are not sure, talk to your doctor or pharmacist before taking Danol.

Take special care with Danol Check with your doctor or pharmacist before taking your medicine if:

- You have any liver or kidney problems
- You have an illness which could be made worse by fluid retention
- You have high blood pressure or heart disease
- You have diabetes
- You have an illness in which the blood gets thicker (called ‘polycythaemia’)
- You have fits (epilepsy)
- You have blood fat problems (called ‘lipid disorders’)
- You have ever had a bad reaction to a hormonal treatment similar to Danol
- You get migraines
- You have cancer or possible breast cancer.

If you are not sure if any of the above apply to you, talk to your doctor or pharmacist before taking Danol.

Taking other medicines

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines. This includes medicines you buy without a prescription, including herbal medicines. This is because Danol can affect the way some other medicines work. Also some medicines can affect the way Danol works.

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

- Steroids such as testosterone, estrogen, progesterone (including ‘the Pill’ or hormone replacement therapy - known as HRT)
- Statins such as simvastatin. Danol may increase the risk of muscle weakness or rapid breakdown of muscle.

Danol may increase the effect of the following medicines:

- Medicines for epilepsy, fits or convulsions (anticonvulsants)
- Medicines used to thin the blood (anti-coagulants such as warfarin)
- Anaesthetics (see ‘Operations or tests’ section below)
- Ciclosporin and tacrolimus - used to stop the rejection of organs after a transplant. Danol 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

Danol may lower the effect of the following medicines:

- Medicines for diabetes
- Medicines for high blood pressure (anti-hypertensives)

- Medicines for migraine

Operations or tests

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

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

Taking Danol with food and drink

Do not drink alcohol while you are taking Danol. This is because drinking alcohol while taking Danol can make you feel sick or short of breath.

Pregnancy and breast-feeding

Do not take Danol if you are pregnant, might become pregnant or think you may be pregnant. If you think you may have become pregnant while taking Danol, stop taking it straight away and talk to your doctor.

Do not breast-feed if you are taking Danol. This is because small amounts may pass into mothers' milk. If you are planning to breast-feed, talk to your doctor or pharmacist. Ask your doctor or pharmacist for advice before taking any medicine if you are pregnant or breast-feeding.

Important information about some of the ingredients of Danol

This medicine contains lactose, which is a type of sugar. If you have been told by your doctor that you cannot tolerate or digest some sugars, talk to your doctor before taking this medicine.

3. How to take Danol

Always take Danol exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

Taking this medicine

- Take this medicine by mouth
- Swallow the capsules whole with a drink of water
- If you feel the effect of your medicine is too weak or too strong, do not change the dose yourself, but ask your doctor
- It is important that you **do not become pregnant** while taking Danol. Start taking the capsules on the first day of your period. 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 Danol has finished

How much to take

The usual dose depends on your needs and the illness being treated:

- Endometriosis: 200 to 800mg a day for three to six months
- Breast cysts: 300mg a day for three to six months

The dose for each day may be split between two and four separate doses.

DO NOT TAKE more than 8 of the 100mg capsules or 4 of the 200mg capsules in one day.

If you take more Danol than you should

If you take more capsules than you should, tell a doctor or go to a hospital casualty department straight away. Take the medicine pack with you. This is so the doctor knows what you have taken.

If you forget to take Danol

If you forget a dose, take it as soon as you remember it. However, if it is nearly time for the next dose, skip the missed dose. Do not take a double dose to make up for a forgotten dose.

If you stop taking Danol

Keep taking Danol until your doctor tells you to stop taking it. Do not stop taking Danol just because you feel better. If you stop your illness may get worse.

Blood tests

Your doctor may carry out regular blood tests to check your liver is working properly and your blood levels are normal. Also, taking Danol may affect the results of some other blood tests.

These include the following tests:

- Hormone testosterone levels
- Liver and thyroid function
- Lipids (fats), sugars and protein levels in your blood

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

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

4. Possible side effects

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

Stop taking Danol and see a doctor or go to a hospital straight away if:

- You have an allergic reaction. The signs may include a rash, swallowing or breathing problems, swelling of your lips, face, throat or tongue
- Pain or tightness in the chest, jaw or arm.
These could be signs of a heart attack

Stop taking Danol and tell a doctor straight away if you notice any of the following side effects (frequency not known) – you may need urgent medical treatment:

- Severe headache and vomiting (being sick)
- Clitoris becomes larger
- Blurred vision, problems with eyesight, difficulty wearing contact lenses
- Liver problems that may cause the eyes or skin to go yellow (jaundice)
- Pain in the liver or liver failure that may cause a swollen abdomen, mental disorientation and confusion (this may be due to a liver injury or non-cancerous liver tumour).
- Pain when moving arms or legs (this may be due to a blood clot)
- Feeling weak together with numb arms or legs which you may not be able to move (this may be a stroke)
- Bruising more easily, getting more infections than usual. These could be signs of a blood problem

Any other severe symptoms which you cannot explain

Tell your doctor as soon as possible if you have any of the following side effects (frequency not known):

- Hair loss (similar to male baldness)
- More hair than usual on the body or face
- Sore throat, hoarse voice or your voice sounds higher or lower than usual
- Skin rashes or blistering. Changes in skin colour or sensitivity to the sun.
- Blood in the urine
- Migraines which are worse than usual
- Your epilepsy gets worse
- Stomach or chest pain

Tell your doctor or pharmacist if any of the following side effects (frequency not known) gets serious or lasts longer than a few days:

- Putting on weight, or increased appetite
- Spots, acne, greasy skin or rashes
- Changes to your menstrual period, vaginal dryness, changes to your sex drive (libido)
- High temperature with skin rashes
- Backache, muscle cramps, twitching of the muscles, pain or swelling in your joints, arms or legs
- Headache, feeling tired
- Flushing
- Feeling depressed, anxious or more nervous than usual
- If your breasts get smaller
- Water retention or bloating
- Feeling sick, dizzy or balance problems (vertigo)
- Palpitations, fast heart beat, high blood pressure
- Lowered fertility in men (may be caused by a lowering in the level of sperm)

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible 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 Danol

Keep this medicine in a safe place where children cannot see or reach it.

Do not use Danol after the expiry date which is stated on the carton and blister. The expiry date refers to the last day of that month.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. Further Information

What Danol contains

- Each 100mg capsule contains 100mg of the active substance, danazol
- Each 200mg capsule contains 200mg of the active substance, danazol
- The other ingredients are maize starch, lactose monohydrate, talc and magnesium stearate. The capsules contain titanium dioxide (E171) and gelatin. The 100mg capsule also contains black iron oxide (E172). The 200mg capsule also contains red iron oxide (E172) and yellow iron oxide (E172). The black ink used to print on the capsules contains shellac, shellac glaze, propylene glycol and black iron oxide (E172).

What Danol looks like and contents of the pack

Danol 100mg capsules are grey and white with D 100 printed on it in black ink.

Danol 200mg capsules are orange and white with D 200 printed on them in black ink. Danol capsules are supplied in cartons of 50, 60 and 100 capsules.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder

Sanofi

410 Thames Valley Park Drive

Reading

Berkshire

RG6 1PT

UK

Tel: 0800 0352525

email: uk-medicalinformation@sanofi.com

Manufacturer

Zentiva, k.s.

U Kabelovny 130

Dolní Mecholupy

102 37, Prague 10

Czech Republic

This leaflet does not contain all the information about your medicine. If you have any questions or are not sure about anything, ask your doctor or pharmacist.

This leaflet was last revised in 11/2020

© *sanofi* , 1974 - 2020