

NEW ZEALAND CONSUMER MEDICINE INFORMATION

AZOL 100 & AZOL 200

Danzaol capsules 100 mg & 200 mg



What is in this leaflet

This leaflet answers some common questions about Azol.

It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you taking Azol against the benefits they expect it will have for you.

If you have any concerns about taking this medicine, ask your doctor or pharmacist.

Keep this leaflet with the medicine. You may need to read it again.

What Azol is used for

Azol is used in the following conditions:

- **Endometriosis** – the inner lining of the uterus (womb) is called the endometrium. Each month, the endometrium is shed as the menstrual period. In endometriosis, a tissue similar to the lining of the uterus also grows outside the uterus, particularly on the ovaries. As this tissue cannot be shed a part of the menstrual period, it causes pain and possibly contributes to infertility.
- **Menorrhagia** - abnormally heavy or long menstrual periods
- **Severe fibrocystic breast disease** – breast lumps or cysts which are very painful

- **Hereditary angioedema** - an inherited condition associated with repeated episodes of stomach upset and swelling of the throat, which may cause difficulty in swallowing or breathing.

Azol contains the active ingredient danazol, which alters the level or the way certain chemicals in the body work.

Ask your doctor if you have any questions about why this medicine has been prescribed for you.

Your doctor may have prescribed it for another reason.

Azol is available only with a doctor's prescription.

Azol is not recommended for use in children, as the safety and effectiveness in children has not been established.

There is no evidence that Azol is addictive.

Before you take Azol

When you must not take it

Do not take Azol if you have an allergy to:

- any medicine containing danazol.
- any of the ingredients listed at the end of this leaflet.
- Some of the symptoms of an allergic reaction may include: hay fever, skin rash, itching or hives.

Do not take Azol if you have any of the following medical conditions:

- Severe liver, kidney or heart disease
- Severe high blood pressure
- Pelvic infection
- Porphyria, a blood disorder
- Blockage of a blood vessel by a clot
- Some cancers, such as cancer of the ovary, womb, cervix, breast or prostate
- Abnormal genital bleeding where the cause is not known.
- Lumps or masses in the ovaries or womb where the cause is not known.

If you are not sure whether any of these apply to you, check with your doctor.

Do not take Azol if you are pregnant.

It is important that you are not pregnant when you start taking Azol, as Azol may cause female babies to develop male physical characteristics.

Do not take Azol if you are breastfeeding.

Azol is not recommended during breastfeeding as it is not known whether it passes into breast milk or what effect it may have on your baby.

Do not take Azol if you have had jaundice while taking birth control pills.

Symptoms of jaundice include yellowing of the skin or eyes.

Do not take Azol after the expiry date printed on the pack or if the packaging is torn or shows signs of tampering.

If you take this medicine after the expiry date, it may not work well.

Do not take Azol if the packaging shows signs of tampering or the capsule do not look quite right.

If you are not sure whether you should start taking this medicine, talk to your doctor.

Before you start to take it

Tell your doctor if you have allergies to any other medicines, foods, preservatives or dyes.

Tell your doctor if you have or have had any of the following medical conditions:

- Diabetes
- Liver or kidney disease
- High blood pressure or heart problems
- Epilepsy, seizures or fits
- Migraine
- Too many red blood cells in the blood (polycythemia).

Your doctor may want to take special care if you have or have had any of these conditions.

Tell your doctor if you are pregnant or plan to become pregnant or are breast-feeding.

You should not fall pregnant during treatment with Azol. The best time to try to get pregnant is after you have completed your course of Azol treatment. You should discuss this with your doctor.

If you become pregnant while taking Azol capsules, stop taking the capsules and see your doctor immediately.

Azol is not recommended while breastfeeding.

Tell your doctor if you have had male-like side effects while you were taking oral contraceptives or other sex hormones.

These effects include hoarseness or deepening of the voice and facial hair.

If you have not told your doctor about any of the above, tell him/her before you start taking Azol.

Taking other medicines

Tell your doctor or pharmacist if you are taking any other medicines, including any that you get without a prescription from your pharmacy, supermarket or health food shop.

Some medicines and Azol may interfere with each other. These include:

- Warfarin, a medicine used to prevent blood clot.
- Insulin and other medicines for diabetes.
- Carbamazepine and phenytoin, medicines used to treat epilepsy.
- Birth control pills, sex hormones.
- Cyclosporin and tacrolimus, medicines used to prevent organ transplant rejection
- Blood pressure medications.

These medicines may be affected by Azol or may affect how well it works. You may need different amounts of your medicines, or you may need to take different medicines. Your doctor can tell you what to do if you are taking any of these medicines.

Your doctor and pharmacist have more information on medicines to be careful with or avoid while taking this medicine.

How to take Azol

Follow all directions given to you by your doctor or pharmacist carefully.

They may differ from the information contained in this leaflet.

If you do not understand the instructions on the bottle, ask your doctor or pharmacist for help.

How much to take

The dose varies from person to person.

Your doctor will tell you how many capsules to take each day and when to take them. This depends on your condition and how you respond to this medicine.

Usually the dose ranges are as follows:

Endometriosis: between 200 mg and 800 mg daily in divided doses. The length of treatment is usually between 3 and 9 months.

Menorrhagia: between 200 mg to 400 mg daily in divided doses. The length of treatment can be up to 6 months depending on how you respond to Azol.

Fibrocystic breast cancer: between 200 mg to 400 mg a day.

Hereditary angioedema: between 200 mg to 600 mg a day.

Azol is not recommended for use in children.

How to take it

Swallow the capsules whole with a full glass of water.

Azol can be taken with or without food.

Women starting Azol should begin treatment during menstruation. It is important that you are not pregnant when starting Azol, and do not become pregnant whilst taking Azol. You should use a non-hormonal barrier method of contraception (such as a condom or diaphragm) while you are taking Azol.

If you forget to take it

If it is almost time for your next dose, skip the dose you missed and take your next dose when you are meant to.

Otherwise, take it as soon as you remember, and then go back to taking your capsules as you would normally.

Do not take a double dose to make up for the dose that you missed.

If you are not sure what to do, ask your doctor or pharmacist.

If you have trouble remembering to take your medicine, ask your pharmacist for some hints.

If you take too much (overdose)

You should only take the number of capsules that you have been told.

Immediately telephone your doctor or the National Poisons Information Centre (0800 POISON

or 0800 764 766) for advice, or go to Accident and Emergency at the nearest hospital, if you think that you or anyone else may have taken too much Azol.

Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

While you are taking Azol

Things you must do

If you are a woman, you should use a non-hormonal, barrier method of contraception (such as condom or diaphragm) while you are being treated with Azol.

Before starting any new medicine, tell your doctor or pharmacist that you are taking Azol.

Tell all the doctors, dentists and pharmacists who are treating you that you are taking Azol.

If you become pregnant while taking Azol, tell your doctor immediately.

If you are about to have any blood tests, tell your doctor that you are taking Azol.

It may interfere with the results of some tests.

If you notice lumps in your breasts that become bigger or do not go away, tell your doctor immediately.

Visit your doctor regularly so that they can check on your progress. Your doctor may want to take some blood tests from time to time. This helps to prevent unwanted side effects.

If you are diabetic, tell your doctor if you notice a change in your blood or urine glucose test results.

Azol can affect blood glucose levels.

Things you must not do

Do not take Azol to treat any other complaints unless your doctor tells you to.

Do not give your medicine to anyone else, even if they have the same condition as you.

Do not stop taking Azol or lower the dosage without checking with your doctor.

If you stop taking it suddenly, your condition may worsen or you may have unwanted side effects such as

If possible, your doctor will gradually reduce the amount you take each day before stopping the medicine completely.

Things to be careful of

Be careful driving or operating machinery until you know how Azol affects you.

Be careful when drinking alcohol while you are taking Azol.

If you feel light-headed, dizzy or faint when getting out of bed or standing up, get up slowly.

Standing up slowly, especially when you get up from bed or chairs, will help your body get used to the change in position and blood pressure. If this problem continues or gets worse, talk to your doctor.

Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking Azol.

Like all other medicines, Azol may have unwanted side effects in some people. Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some of the side effects.

Do not be alarmed by the following lists of side effects. You may not experience any of them.

Ask your doctor or pharmacist to answer any questions you may have.

Tell your doctor or pharmacist if you notice any of the following and they worry you:

- Feeling sick (nausea), vomiting, indigestion, constipation.
- Weight gain
- Swelling of the hands, ankles or feet
- Acne, oily skin
- Muscle cramps, joint pain
- Hot flushes, sweating
- Skin rash, itching
- Hair loss
- Mood changes, feeling irritable, depression
- Headache
- Dizziness, weakness
- Sleep problems
- Blood in the urine.

The above list includes the more common side effects of your medicine.

Women can also expect disturbances in their menstrual cycle such as spotting changes in the timing of periods or having no periods. Vaginal dryness and irritation and changes in breast size may also occur.

Abnormalities in semen volume, sperm count and motility may occur in males on long term treatment with Azol.

Tell your doctor as soon as possible if you notice any of the following:

- Facial hair in women.
- Voice deepening or hoarseness in women
- Enlarged clitoris
- Symptoms of sunburn (such as redness, itching, swelling, blistering) which may occur more quickly than normal
- Yellowing of the eyes or skin.

The above list includes serious side effects that may require medical attention.

If any of the following happen, tell your doctor immediately or go to Accident and Emergency at your nearest hospital:

- Problems with your vision such as blurred vision or difficulty focusing
- Persistent headache
- Chest pain

- Measles-like rash, often with fever, sore throat, headache, diarrhoea
- Severe blisters and bleeding in the lips, eyes, mouth, nose and genitals
- Pain or swelling and redness in the legs
- Difficulty breathing.

These are very serious side effects and you should stop taking Azol immediately and consult your doctor.

Serious side effects are rare.

Tell your doctor or pharmacist if you notice anything that is making you feel unwell.

Other side effects not listed above may also occur in some people.

After using Azol

Storage

Keep it where children cannot reach it.

A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

Keep your capsules in the bottle until it is time to take them.

If you take the capsules out of the bottle they may not keep well.

Keep your capsules in a cool dry place where the temperature stays below 30°C.

Do not store Azol or any other medicine in the bathroom or near a sink.

Do not leave it on a window sill or in the car.

Heat and dampness can destroy some medicines.

Disposal

If your doctor tells you to stop taking Azol or the expiry date has passed, ask your pharmacist what to do with any medicine that is left over.

Product description

What it looks like

Azol comes in 2 strengths of capsules:

- Azol 100 capsule – light grey body with dark grey cap, marked G on the cap and DL100 on the body in black.
- Azol 200 capsule – white body with orange cap, marked G on the cap and DL200 on the body in the black.

Ingredients

The active ingredient in Azol is danazol.

- Each Azol 100 capsule contains 100 mg of danazol
- Each Azol 200 capsule contains 200 mg of danazol.

The capsules also contain:

- Lactose
- Microcrystalline cellulose
- Silicon dioxide colloidal
- Povidone
- Sodium starch glycollate
- Sodium lauryl sulfate
- Magnesium stearate
- Gelatin
- Titanium dioxide
- Black iron oxide (Azol 100 only)
- FD & C Red 3 (Azol 200 only)
- Red iron oxide (Azol 200 only)
- Yellow iron oxide (Azol 200 only)
- Printing ink

The capsules are gluten free.

If you want to know more

Should you have any questions regarding this product, please contact your pharmacist or doctor.

Who supplies this medicine

Distributed in New Zealand by:

Mylan New Zealand Ltd,
PO Box 11183,

Ellerslie,
Auckland.

Telephone: (09) 579 2792

Date of Information

18 April 2018

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