

Azol

contains the active ingredient danazol

CONSUMER MEDICINE INFORMATION

What is in this leaflet

This leaflet answers some common questions about Azol.

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

All medicines have benefits and risks. Your doctor has weighed the risks of you taking Azol against the benefits expected for you.

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

Keep this leaflet with your medicine.

You may need to read it again.

What Azol is used for

Azol is used in the following conditions:

- Endometriosis - a condition in which tissue similar to the lining of the uterus (womb) grows outside the uterus causing pain or bleeding
- Menorrhagia - abnormally heavy during menstruation
- Severe fibrocystic breast disease - lumps or cysts in the breast which are very painful
- Hereditary angioedema - an inherited condition associated with repeated episodes of stomach upset and swelling of the throat.

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 Azol has been prescribed for you.

Your doctor may have prescribed Azol for another reason.

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

Azol is available only with a doctor's prescription.

There is no evidence that Azol is addictive.

Before you take Azol

When you must not take it

Do not take Azol if you are allergic to medicines containing danazol or any of the ingredients listed at the end of this leaflet.

Some of the symptoms of an allergic reaction may include hayfever, skin rash, itching or hives.

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

- severe liver, kidney or heart disease
- very high blood pressure
- pelvic infection
- porphyria - a blood disorder
- previous or present blockage of a blood vessel by a clot
- cancer of the ovary, womb, cervix, breast or prostate
- undiagnosed abnormal genital bleeding

- undiagnosed lumps or masses in the ovaries or womb
- past jaundice due to oral contraceptives.

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 the expiry date (EXP) printed on the pack has passed.

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

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

Before you start to take it

Tell your doctor if you are allergic to any other medicines, foods, dyes or preservatives.

Tell your doctor if you plan to become pregnant or breastfeed.

Azol is not recommended during pregnancy or breastfeeding.

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

- diabetes
- liver or kidney disease
- high blood pressure or heart problems

- lipid disorders - blood fat abnormalities
- epilepsy - seizures or fits
- migraine
- polycythemia - too many red blood cells in the blood
- previous bad reaction to Azol or any similar treatment.

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

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 them before you start taking Azol.

Taking other medicines

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

Some medicines may be affected by Azol, or may affect how well it works. These include:

- warfarin - a medicine used to prevent blood clots
- insulin and other medicines for diabetes
- medicines used for high blood pressure
- carbamazepine and phenytoin - medicines used to treat epilepsy
- oral contraceptives (birth control pills), sex hormones
- ciclosporin and tacrolimus - medicines used to prevent organ transplant rejection.

Your doctor can tell you what to do if you are taking any of these medicines.

If you are not sure whether you are taking any of these medicines, check with your doctor or pharmacist.

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

How to take Azol

Follow all directions given to you by your doctor and 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.

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.

Dose ranges are as follows:

- endometriosis, between 200 and 800 mg a day
- menorrhagia, between 200 to 400 mg a day
- hereditary angioedema, between 200 and 600 mg a day
- fibrocystic breast disease, between 200 and 400 mg a day.

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.

Azol is not recommended for use in children.

How to take Azol

Swallow the capsules with a glass of water.

Azol can be taken with or without food.

If you forget to take Azol

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 the missed dose 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 you missed.

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

If you take too much Azol (overdose)

Immediately telephone your doctor, or the Poisons Information Centre (telephone 13 11 26), or go to Accident and Emergency at the nearest hospital, if you think 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 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 a condom or diaphragm) while you are being treated with Azol.

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

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 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.

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

Azol may affect the results of some tests.

Things you must not do

Do not use Azol to treat any other conditions unless your doctor tells you to.

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

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.

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

Do not be alarmed by this list of possible side effects.

You may not experience any of them.

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

- nausea (feeling sick), vomiting, indigestion, constipation
- weight gain
- muscle cramps
- joint, back or neck pain
- hot flushes, sweating
- headache

- changes in appetite
- menstrual disturbances such as spotting, irregular periods, no periods
- vaginal dryness and irritation.

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

Tell your doctor immediately if you notice any of the following:

- gradual blurring or loss of vision
- acne, oily skin or hair
- facial hair in women
- voice deepening or hoarseness in women
- enlarged clitoris
- decrease in testicle size
- continuing pain or tenderness in abdomen or stomach
- anxiety, depression
- symptoms of sunburn such as redness, itching, swelling, blistering, which may occur more quickly than normal
- yellowing of the eyes or skin, dark coloured urine, light coloured stools, continuing loss of appetite
- bleeding or bruising more easily than normal
- frequent infections such as fever, severe chills, sore throat or mouth ulcers
- worsening of epilepsy.

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

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

- problems with your vision such as blurred vision or difficulty focusing, with headache, nausea, vomiting
- chest pain
- skin rash, itching or hives
- 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.

The above list includes very serious side effects. You may need urgent medical attention or hospitalisation.

Tell your doctor 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 Azol 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 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 Azol in the car or on window sills.

Heat and dampness can destroy some medicines.

Disposal

If your doctor tells you to stop taking Azol, or your capsules have passed their expiry date, ask your pharmacist what to do with any that are left over.

Product description

What it looks like

Azol is available in 2 capsule strengths:

- Azol 100 - dark grey and light grey capsule printed G and DL100
- Azol 200 - orange and white capsule printed G and DL200.

Each bottle contains 100 capsules.

This leaflet was prepared on
28 August 2019.

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 the following inactive ingredients:

- lactose
- lactose monohydrate
- microcrystalline cellulose
- colloidal anhydrous silica
- povidone
- sodium starch glycollate
- sodium lauryl sulfate
- magnesium stearate
- titanium dioxide
- gelatin
- iron oxide black [Azol 100 only]
- erythrosine [Azol 200 only]
- iron oxide red [Azol 200 only]
- iron oxide yellow [Azol 200 only].

The capsules are gluten free.

Manufacturer

Azol is made in Australia by:

Alphapharm Pty Limited

Level 1, 30 The Bond

30-34 Hickson Road

Millers Point NSW 2000

www.mylan.com.au

Australian registration numbers:

Azol 100 - AUST R 10001

Azol 200 - AUST R 10011