

ANDROCUR®-100

(ANNE-dro-cur)
cyproterone acetate

Consumer Medicine Information

WHAT IS IN THIS LEAFLET

This leaflet answers some common questions about Androcur-100.

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 Androcur-100 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 ANDROCUR-100 IS USED FOR

Androcur-100 is an anti-androgen medicine. Androgens such as testosterone are natural male sex hormones. In some types of prostate cancer, androgens may help the cancer cells to grow. By blocking these hormones, Androcur-100 may slow or stop the growth of cancer.

Androcur-100 may be used in combination with other medicines or following surgical removal of the testes to treat side effects such as "hot flushes" or "sweats" and to prevent any initial worsening of the disease.

Androcur-100 should only be taken by men. It should not be taken by women or children and adolescents below 18 years of age.

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.

This medicine is available only with a doctor's prescription.

BEFORE YOU TAKE ANDROCUR-100

When you must not take it

Do not take Androcur-100 if you have an allergy to:

- cyproterone acetate, the active ingredient in Androcur-100
- any of the ingredients listed at the end of this leaflet

Some of the symptoms of an allergic reaction may include:

- shortness of breath
- wheezing or difficulty breathing
- swelling of the face, lips, tongue or other parts of the body
- rash, itching or hives on the skin

Do not take Androcur-100 if you have any of the following medical conditions:

- liver disease, previous or existing liver tumours
- existing blood clots
- severe chronic depression

- Dubin-Johnson syndrome or Rotor syndrome (your doctor would have told you if you have either of these conditions)
- Wasting disease (with the exception of cancer of the prostate)

Do not take this medicine after the expiry date printed on the pack and blister.

The expiry date is printed on the carton and on each blister after "EXP" (e.g. 11 09 refers to November 2009). The expiry date refers to the last day of that month. If it has expired return it to your pharmacist for disposal.

Do not take this medicine if the packaging is torn or shows signs of tampering.

If the packaging is damaged, return it to your pharmacist for disposal.

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 medical conditions, especially the following:

- diabetes
- history of blood clotting or sickle cell anaemia
- osteoporosis, a family history of osteoporosis or risk factors for developing osteoporosis (such as smoking, a diet low in calcium, poor mobility, a slight build or treatment with steroid medicines)

Tell your doctor if fertility after treatment is important.

In this case it is advisable to have a spermatogram before taking Androcur-100 to establish your fertility before commencing therapy. It can take 3-20 months for fertile sperm production to be re-established after stopping this medicine.

If you have not told your doctor about any of the above, tell them before you start taking Androcur-100.

Taking other medicines

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

Some medicines and Androcur-100 may interfere with each other. These include:

- phenytoin, a medicine used to treat epilepsy
- medicines used to treat fungal infections, including ketoconazole, itraconazole, clotrimazole
- ritonavir, a medicine used in the treatment of HIV
- rifampicin, a bactericidal antibiotic used to treat infections such as tuberculosis and leprosy
- St John's wort, a herbal remedy used to treat mood disorders
- Statins (HMGCoA inhibitors), medicines used to lower cholesterol levels in people with or at risk of cardiovascular disease
- medicines used to treat diabetes

These medicines may be affected by Androcur-100, or may affect how well it works. You may need different amounts of your medicine, or you may need to take different medicines.

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

HOW TO TAKE ANDROCUR-100

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 printed on the pharmacist label, ask your doctor or pharmacist for help.

How much to take

Your doctor will tell you the dose that you should take. The usual daily dose is 50-300 mg (half to three tablets) of Androcur-100. Your doctor may request you take Androcur-100 with other medicines and/or change your dose during treatment.

Do not alter the dose yourself.

Your doctor will advise you if changing the dose is necessary.

How to take it

Swallow the tablets whole with some liquid after meals.

When to take it

Take your medicine after meals at about the same time each day.

Taking it at the same time each day will have the best effect. It will also help you remember when to take it. Missed Androcur-100 tablets may diminish the effectiveness of treatment.

How long to take it

Continue taking your medicine for as long as your doctor tells you.

This medicine helps to control your condition, but does not cure it. It is important to keep taking your medicine even if you feel well.

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 medicine as you would normally.

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

This may increase the chance of you getting an unwanted side effect.

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)

Immediately telephone your doctor or the Poisons Information Centre on 13 11 26 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 Androcur-100. Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

WHILE YOU ARE TAKING ANDROCUR-100

Things you must do

If you are about to be started on any new medicine, remind your doctor and pharmacist that you are taking Androcur-100.

Tell any other doctors, dentists, and pharmacists who treat you that you are taking this medicine.

Keep all of your doctor's appointments so that your progress can be checked.

Your doctor may do some tests from time to time to make sure the medicine is working and to prevent unwanted side effects.

Things you must not do

Do not take Androcur-100 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 your medicine 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.

Things to be careful of

Be careful driving or operating machinery until you know how Androcur-100 affects you.

This medicine may cause tiredness, diminished vitality and can impair the ability to concentrate. If you have any of these symptoms, do not drive, operate machinery or do anything else that could be dangerous.

Be careful when drinking alcohol while you are taking this medicine.

If you drink alcohol, tiredness, diminished vitality and the ability to concentrate may be worse.

SIDE EFFECTS

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking Androcur-100.

All medicines can have side effects. 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:

- tiredness
- weight increase
- decreased sexual drive
- headache
- depressive mood
- fast heart beat
- nausea and other gastrointestinal complaints
- breast pain, change in breast size, breast swelling and/or tenderness

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

If you were fertile before treatment, Androcur-100 will also normally result in your inability to produce sperm (infertility). Fertility is usually regained within a few months of discontinuing therapy.

Androcur-100 will also normally result in the inability to get or maintain an erection (impotence). This ability is usually also regained within a few months of discontinuing therapy.

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

- yellowing of the skin and/or eyes
- light coloured bowel motions, dark coloured urine
- severe upper abdominal pain
- shortness of breath
- vomiting blood or material that looks like coffee grounds, bleeding from the back passage, black sticky bowel motions (stools) or bloody diarrhoea.

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

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

- sudden severe headache, loss of vision, loss of coordination, slurred speech, shortness of breath, chest pain, numbness heat or swelling

The above is a serious

side effect. You may need urgent medical attention or hospitalisation.

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

Other side effects not listed above may happen in some people.

AFTER TAKING ANDROCUR-100

Storage

Keep your tablets in the pack until it is time to take them.

If you take the tablets out of the pack, they may not keep well.

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

Do not store Androcur-100 or any other medicine in the bathroom, near a sink or on a window-sill.

Do not leave it in the car.

Heat and damp can destroy some medicines.

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.

Disposal

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

Return any unused medicine to your pharmacist.

PRODUCT DESCRIPTION

What it looks like

Androcur-100 tablets are capsule shaped white scored tablets presented in blisters of 10. Each pack contains 50 tablets.

Ingredients

Active ingredient per tablet:

- Androcur 100 - 100 mg of cyproterone acetate

Inactive ingredients:

- lactose
- corn starch
- povidone
- magnesium stearate

Supplier

Made in France for:

Bayer Australia Limited

ABN 22 000 138 714

875 Pacific Highway

Pymble NSW 2073

Australian Registration Number

Androcur-100: AUST R 51449

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(www.bayer.com.au) for latest
Australian Consumer Medicine
Information.

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