

Anandron(R)

Nilutamide

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about Anandron. 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 Anandron against the benefits Anandron is expected to have for you.

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

Keep this leaflet with the medicine.

You may need to read it again.

What Anandron is used for

Anandron is a medicine for treating prostate cancer in men. It contains the active ingredient nilutamide.

Anandron belongs to a family of medicines called non-steroidal anti-androgens. These medicines work by blocking the effect of androgen hormones that are naturally produced by your body. Prostate cancer cells are dependent on these hormones, and blocking their effect is intended to stop the growth of the cancer.

Anandron is more effective when used at the same time as other medicines known generally as LHRH agonists or, alternatively, following surgery designed to treat prostate

cancer.

Your doctor may have prescribed Anandron for another reason. Ask your doctor if you have any questions about why Anandron has been prescribed for you.

Anandron is available only with a doctor's prescription.

Before you take Anandron

When you must not take it

Anandron must only be taken by men. It is not suitable for women or children.

Do not take Anandron if:

1. you have an allergy to:

- * Nilutamide or any of the other ingredients listed at the end of this leaflet (see Product Description).

Symptoms of an allergic reaction to these medicines may include:

- * asthma, wheezing or shortness of breath
- * swelling of the face, lips or tongue which may cause difficulty in swallowing or breathing
- * hives, itching or skin rash
- * fainting

2. you have severe liver problems

3. you have severe breathing problems

4. you have previously taken another anti-androgen medicine for prostate cancer

that did not work

If you are not sure whether you should start taking Anandron, contact your doctor.

Return the pack to your pharmacist for replacement if:

- 1. the packaging is torn or shows signs of tampering**
- 2. the expiry date on the pack has passed.**

If you take Anandron after the expiry date has passed, it may not work as well.

Before you start to take it

Tell your doctor if:

1. you have any allergies to:

- * any other medicines
- * any other substances, such as lactose or corn (maize)

2. you have or have had any of the following medical conditions:

- * liver disease
- * breathing problems

If you have not told your doctor about any of the above, tell them before you take any Anandron.

Taking other medicines and drinking alcohol

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

Anandron may interfere with some medicines, including the following:

- * warfarin or phenindione (medicines used to stop blood clots)

- * phenytoin (a medicine used to treat epilepsy)
- * propranolol (a medicine used to treat high blood pressure and some other conditions)
- * diazepam or chlordiazepoxide (medicines for anxiety)
- * theophylline (a medicine used to treat asthma)

Check the labels on your medicines for these drug names or ask your pharmacist for help. Tell your doctor if you are taking any of these medicines before you start taking Anandron.

Some patients being treated with Anandron may have hot flushes or feel unwell after drinking alcohol. This is known as alcohol intolerance and may impair your ability to drive or operate machinery. If this happens, you should not drink alcohol while taking Anandron.

Your doctor or pharmacist has more information on medicines to be careful with or avoid while taking Anandron.

How to take Anandron

How much to take

Follow all directions given to you by your doctor and pharmacist carefully. These directions may differ from the information contained in this leaflet.

The usual dosage of Anandron is one tablet twice daily (or two tablets once daily) for the first four weeks and then one tablet once daily thereafter.

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

How to take it

You should swallow each tablet whole with some water. Do not chew them.

When to take it

You can take Anandron with or without food.

How long to take it for

Do not take Anandron for longer than your doctor says. If you are not sure how long to take Anandron, ask your doctor.

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 tablets as you would normally.

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

If you are not sure whether to skip the dose, talk to your doctor or pharmacist.

If you take too much (overdose)

Immediately telephone your doctor or Poisons Information Centre (Telephone 13 11 26), or go to Accident & Emergency at your nearest hospital, if you think that you or anyone else may have taken too much Anandron. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

While you are taking Anandron

Things you must do

Tell your doctor immediately if you experience any breathing problems or a worsening of a pre-existing breathing problem. Symptoms may include shortness of breath, coughing, chest pain or fever.

Tell your doctor immediately if you experience nausea, vomiting,

abdominal pain and jaundice (yellow eyes/skin).

If you are about to be started on any new medicine, tell your doctor and pharmacist that you are taking Anandron.

Things you must not do

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

Do not take Anandron to treat any other complaints unless your doctor says to.

You should not stop taking Anandron without consulting your doctor first.

Things to be careful of

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

Anandron may cause dizziness or light-headedness in some people. Make sure you know how you react to Anandron before you drive a car, operate machinery or do anything else that could be dangerous if you are dizzy or light-headed. If you drink alcohol, dizziness or light-headedness may be worse.

Side Effects

Anandron helps most people with prostate cancer, but it may have unwanted side-effects in some people.

All medicines may cause side effects. Sometimes they are serious, but most of the time they are not. You may need medical treatment for some of the side-effects that have been seen in patients taking Anandron.

Most side effects caused by Anandron happen early in the course of treatment and usually lessen after four weeks when the dose is normally reduced to one tablet daily. The most common side effect affects the eyes and makes it difficult to

adapt to darkness. This problem is almost always temporary and may be improved by wearing tinted glasses (eg. sunglasses). Until your eyes get used to darkness, you should not drive at night or through tunnels in bright light.

Tell your doctor if you experience any of the following side effects and it worries you:

- * nausea or vomiting
- * difficulty adapting to changes in light
- * dizziness

Your doctor may be able to adjust your treatment or give you advice to make these side effects less troublesome.

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

- * any new breathing problem or chest pain, or a worsening of a pre-existing breathing problem
- * jaundice (yellow eyes/skin) possibly with nausea, vomiting and abdominal pain
- * allergic reactions such as asthma, wheezing, shortness of breath, swelling of the face, lips or tongue, hives, itching, skin rash or fainting

You may need urgent medical attention for these rare serious side effects.

Other side effects not listed above may occur in some patients, so you should tell your doctor if you feel unwell while taking Anandron.

Do not be alarmed by this list of possible side effects. You may not experience any of them. Ask your doctor or pharmacist to answer any questions you may have.

After using Anandron

Storage

Keep your tablets in the blister strip until it is time to take one.

If you take the tablets out of the blister strip, they may not keep as well.

Store Anandron tablets in a cool dry place where the temperature stays below 30 degrees C. Do not store them or any other medicine in the bathroom or near a sink. Do not leave the tablets in the car or on window sills.

Heat and dampness can destroy some medicines.

Keep Anandron where children cannot reach it.

A locked cupboard at least one-and-a-half metres (about 5 feet) above the ground is a good place to store medicines.

Disposal

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

Product description

What Anandron looks like

Anandron 150 mg tablets are white to off-white tablets, marked with 168D on one side and RU on the reverse. They come in packs of 30 tablets.

Ingredients

The active ingredient in Anandron tablets is nilutamide. There is 150 mg of nilutamide in every Anandron tablet. Each tablet also contains some inactive ingredients. These are: maize starch, lactose, povidone, sodium docusate, magnesium stearate and talc.

Anandron does not contain gluten, sucrose, tartrazine or any other azo dyes.

Manufacturer/Distributor

Anandron tablets are distributed by:

Aventis Pharma Pty Ltd
27 Sirius Road,
Lane Cove NSW Australia

Australian registration number:
AUST R 55059

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