

PrAnandron®

Nilutamide tablets

50 mg

Nonsteroidal antiandrogen

INFORMATION FOR THE PATIENT

How to make ANANDRON work best for you

Your doctor has decided that ANANDRON is the best treatment for you. Remember that the chances of controlling your illness are greater if you cooperate fully with your doctor and try to become well informed about your condition.

This leaflet is intended to provide you with only brief advice about ANANDRON tablets. It does not take the place of your doctor's advice or your pharmacist's advice. Your doctor knows and understands your personal condition; be sure to follow your doctor's instructions carefully and read any materials he gives you. If you have any questions after reading this information leaflet, be sure to ask your doctor or pharmacist. Please note that both your doctor and pharmacist have much more information about ANANDRON than the information contained in this brief leaflet.

Keep this leaflet with the medicine as you may need to use it again.

What is ANANDRON and how does it work?

ANANDRON belongs to a group of medicines called "antiandrogens". It blocks the effect of hormones called androgens, which are naturally produced by your body. By blocking the effect of androgens, ANANDRON may help slow down the disease in your prostate gland. It will also help to reduce the symptoms you experience because of this disease.

What does ANANDRON contain?

ANANDRON tablets contain the active ingredient nilutamide. Each tablet contains 50 mg of nilutamide. ANANDRON tablets contain lactose.

ANANDRON tablets are white to off-white in colour and are debossed with "168" over "A" on one side and with the Roussel logo on the other side.

How should you take ANANDRON to make it work best for you?

- Take ANANDRON tablets exactly as your doctor has told you. Do not take more or less of it. Do not take it more often. Do not take it for a longer period of time than your doctor ordered.
- Take your dose by mouth, once a day before breakfast.
- The usual starting dose is 300 mg (6 tablets) per day for the first four weeks. Your dose of ANANDRON may then be decreased to 150 mg (3 tablets) every day.

Your doctor will decide your dose, your schedule, and for how long you need to take ANANDRON. This will depend on your disease condition and on whether you experience side-effects. Talk to your doctor if you have questions about this.

What to do if you miss a dose?

If you miss a dose, take it as soon as you remember and then resume your normal dosing schedule. However, you should not take more than 300 mg of ANANDRON in any one day during the first four weeks of treatment or more than 150 mg in any one day thereafter. Therefore, if it is almost time

for your next dose when you remember ²⁸⁰⁵⁸⁸⁶⁰ that you have missed a dose, skip the dose you missed and take your next dose at the usual time (i.e. do not take a double dose). If you are concerned or if you have missed more than one dose, please speak to your doctor.

What to do if you take too many tablets?

In case of drug overdose, contact a health care practitioner, hospital emergency department or regional Poison Control Centre immediately, even if there are no symptoms.

If you take, by mistake, too many tablets on the same day, you may feel nauseous and dizzy, and you may vomit. These symptoms will normally go away after temporarily interrupting your treatment or reducing the dose, however these steps should only be taken on your doctor's advice. If you have taken more than 300 mg in one day, you should contact your doctor as soon as possible.

Does ANANDRON have side effects?

The various treatments of disease of the prostate, such as yours, can all cause hot flushes, decrease in sex drive, or impotence.

ANANDRON is usually well tolerated but like any other medicine, can cause side effects. Most side effects with ANANDRON occur early in the course of treatment and will usually lessen after four weeks when the dose is normally reduced to 150 mg daily.

The most common side effects affect the eyes. You may notice that your eyes require more time to adapt to darkness, especially when there is a sudden change in lighting (for example, driving through a tunnel). When it occurs, this problem is almost always temporary and may be improved by wearing tinted glasses. However, until your eyes accommodate better to the dark, you should be very careful when driving or operating machinery.

Some patients may develop breathing problems or a worsening of a pre-existing breathing problem. Symptoms may include shortness of breath, coughing, chest pain and fever. Fatal cases due to pulmonary problems have been reported during ANANDRON treatment. It is important that you contact your doctor immediately if you have any breathing difficulties while taking ANANDRON.

In rare cases, ANANDRON may cause an increase in liver tests and, very rarely, hepatitis. Symptoms that may suggest a liver problem include: persistent lack of appetite, nausea (queasiness), vomiting, abdominal pain or tenderness, jaundice (yellow eyes and/or skin), dark urine, itching or unexplained flu-like symptoms. You should advise your doctor promptly if you develop any of these symptoms.

ANANDRON can also cause nausea and vomiting which are not related to liver problems. It can also cause dizziness. In most cases, these symptoms will improve following dosage reduction which normally occurs after four weeks of treatment. However, you should inform your doctor as soon as possible if you experience vomiting because it may be preferable to lower your dose earlier.

You should talk to your doctor or pharmacist if you have severe bone pain during treatment with ANANDRON.

Tell a doctor or pharmacist if you feel a very fast, uneven or forceful heartbeat



(palpitations), shortness of breath, chest discomfort, or if you feel faint during treatment with ANANDRON.

In some patients with metastatic prostate cancer, antiandrogen drugs, like ANANDRON may promote, rather than slow down, the disease. Your doctor may advise you to stop your treatment with ANANDRON in case of worsening of the disease. Your condition should be monitored prior starting a new treatment.

If you think that you are reacting badly to ANANDRON, please tell your doctor. This is especially important if you have any problem that is not mentioned in this leaflet.

Can you take ANANDRON with alcohol and other medicines?

Some patients being treated with ANANDRON may have hot flushes or feel unwell after drinking alcohol. This is known as alcohol intolerance. If this happens to you, you should avoid alcohol completely. Please contact your doctor or pharmacist for advice.

ANANDRON may interfere or cause problems with other medicines that you are taking, so it is important that you tell your doctor and pharmacist about all of the medicines that you are taking, including those you have obtained without a prescription.

Drugs that may interact with ANANDRON include, but are not limited to:

- drugs used to thin the blood, such as: warfarin or nicoumalone
- drugs used to treat epilepsy, such as: phenytoin
- drugs used to treat hypertension (high blood pressure), angina, migraine or other conditions, such as: propranolol
- anti-anxiety drugs, such as: chlordiazepoxide or diazepam
- anti-asthma drugs, such as: theophylline
- antiarrhythmic drugs (used to treat abnormal heart rhythm) such as: quinidine, disopyramide, amiodarone, sotalol, dofetilide, ibutilide, dronedarone, flecainide, propafenone
- antipsychotic drugs (used to treat mental disorders) such as: chlorpromazine
- antidepressant drugs (used to treat depression) such as: amitriptyline, nortriptyline
- opioid drugs, such as: methadone
- antibiotics, such as: erythromycin, clarithromycin, azithromycin, moxifloxacin
- antifungals
- antimalarials, such as: quinine
- drugs belonging to a class called beta-2 agonists, such as: salbutamol
- drugs belonging to a class called 5-HT₃ antagonists, such as: ondansetron.

Your doctor will be able to advise you what to do if you are taking any of these medicines. Your doctor may also perform some blood tests.

What should you remember?

Before taking this medication tell your doctor and pharmacist if:

- you have previously been treated for your prostate condition with a hormone, and the treatment did not work;

- you have liver or breathing problems. You should not take ANANDRON if you have either a severe liver or severe breathing disorder. Please discuss this with your doctor if you believe that you have either of these conditions;
- you have lactose intolerance;
- you are taking any other medication;
- you have low red blood cell count (anemia);
- you have family history of severe osteoporosis, have low bone mineral density, if you are taking any medication that can cause thinning of the bones (such as corticosteroids or anti-convulsive (anti-seizure) medication), or if you use alcohol or tobacco. ANANDRON may increase your risk of bone thinning (osteoporosis) and bone fractures;
- you have heart disease, or a heart condition called “Long QT syndrome”;
- you have diabetes (high blood sugar). ANANDRON may affect your blood glucose level and you may need to test your blood sugar more frequently while taking ANANDRON;
- you have any other medical problem(s).

While taking this medication

- Report any unusual reactions to your doctor without delay. This is important as it will aid in the early detection and prevention of potential complications;
- ANANDRON is intended for the treatment of prostate disease in men and therefore should not be taken under any circumstances by women or by children;
- Keep ANANDRON at room temperature between 15 and 30°C. Protect the tablets from excessive heat, light and humidity. As with all medicines, you should store the tablets in the original pharmacist container and out of the reach of children;
- If you require more information on this drug, consult your doctor or pharmacist.

What else do you need to know?

Return any unused or expired ANANDRON tablets to your pharmacist for disposal.

Date of Revision:

Manufacturer: CHEPLAPHARM Arzneimittel GmbH, Ziegelhof 24, 17489 Greifswald, Germany

Importer / Distributor: Xediton Pharmaceuticals Inc., 2000 Argentia Road, Mississauga, Ontario L5N1W1

Questions or concerns: 1-888-XEDITON

90003047/10