

PART III: CONSUMER INFORMATION

^{Pr}ANDROCUR[®]

cyproterone acetate tablets

^{Pr}ANDROCUR[®] DEPOT

cyproterone acetate injection

This leaflet is Part 3 of a three-part "Product Monograph" published when ANDROCUR was approved for sale in Canada and is designed specifically for Consumers. This leaflet is a summary and will not tell you everything about ANDROCUR. Contact your doctor or pharmacist if you have any questions about the drug.

ABOUT THIS MEDICATION

What the medication is used for:

ANDROCUR is indicated for the palliative treatment of patients with advanced prostate cancer.

What it does:

ANDROCUR is a drug acting against male sex hormones (androgens). Androgens encourage the growth of prostate cancer and ANDROCUR inhibits this effect.

When it should not be used:

Do not take ANDROCUR if you:

- are allergic (hypersensitive) to cyproterone acetate or any of the other ingredients of ANDROCUR;
- have a liver disease or reduced liver function;
- have Dubin-Johnson syndrome or Rotor syndrome that affects the excretion of red blood cell pigment (bilirubin);
- have or have had liver tumors that are not due to the spread of prostate cancer;
- have or ever had a benign brain tumor (meningioma)
- have wasting diseases that are not related to prostate cancer;
- suffer from severe chronic depression;
- have conditions that increase your risk for developing blood clots (thromboembolic process).

What the medicinal ingredient is:

Cyproterone acetate

What the nonmedicinal ingredients are:

The other tablet ingredients are colloidal anhydrous silica, corn starch, lactose monohydrate, magnesium stearate, and povidone 25

The other solution ingredients are castor oil for injection, benzyl benzoate.

What dosage forms it comes in:

ANDROCUR is supplied in 2 forms:

Tablet: Each tablet contains 50 mg cyproterone acetate

Solution: Each 3 mL ampoule contains 100 mg/mL cyproterone acetate in oily solution

WARNINGS AND PRECAUTIONS

Serious Warnings and Precautions

ANDROCUR and ANDROCUR DEPOT should be prescribed and managed by a doctor experienced with the treatment of prostate cancer.

Possible serious side effects of ANDROCUR include:

- **Liver damage and liver failure**

BEFORE you use ANDROCUR talk to your doctor or pharmacist if you have or have had any of the following conditions:

- Blood clots;
- Liver problem;
- Depression;
- Breathing problem (shortness of breath).
- Diabetes. Your doctor may need to adjust your antidiabetic medication. This requires strict supervision during treatment with ANDROCUR.
- Anemia. Your doctor will monitor your red-blood cell count during treatment.
- History of benign brain tumors (meningiomas)

ANDROCUR may decrease the function of the hormone-producing glands attached to the kidney (adrenal glands).

Benign brain tumours (single and multiple meningiomas) have been reported with long-term treatment of ANDROCUR, and very rarely in patients after several months of treatment with ANDROCUR for prostate cancer.

ANDROCUR DEPOT needs to be injected very slowly into the muscle to prevent pulmonary oil microembolism (oily solution gets into the lung) and post-injection reactions (vasovagal reactions). See SIDE EFFECTS AND WHAT TO DO ABOUT THEM for symptoms.

ANDROCUR is not recommended for use in children and adolescents below 18 years of age and before the end of puberty, as it may have a negative effect on growth and the immature hormonal regulation functions.

ANDROCUR is not recommended for use in women.

Based on an analysis of the results of several older studies, long-term combination therapy of ANDROCUR with either orchiectomy (removal of testicles) or a GnRH agonist (one class of drug that acts against male sex hormones) in advanced prostate cancer may result in a 5-year survival disadvantage compared to castration alone.

INTERACTIONS WITH THIS MEDICATION

Drugs that may interact with ANDROCUR include:

- Statins (medicines for reducing blood fats)
- Ketoconazole, itraconazole, clotrimazole (for fungal infections)
- Ritonavir (for viral infections)
- Rifampicin (for tuberculosis)
- Phenytoin (for epilepsy)
- St. John's Wort (herbal remedy for depression)

PROPER USE OF THIS MEDICATION

You should follow the dose prescribed by your doctor.

Usual dose

ANDROCUR Tablet

200 mg to 300 mg daily taken orally in two or three divided doses with liquid after meals. Maximum daily dose is 300 mg. After orchiectomy (removal of testicles), a lower daily dose of 2 to 4 tablets (100-200 mg) is recommended.

ANDROCUR DEPOT Injection

300 mg once a week. After orchiectomy, 300 mg once every two weeks. ANDROCUR DEPOT is to be given slowly into a muscle (intramuscular).

Overdose

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.

Missed Dose

ANDROCUR Tablet

Do not take the missed ANDROCUR tablet (do not take a double dose to make up for the missed tablet). Continue taking the tablets at the regular time.

ANDROCUR DEPOT Injection

Have a new appointment with your doctor in order to make up for the forgotten injection. You should not get a double dose.

SIDE EFFECTS AND WHAT TO DO ABOUT THEM

ANDROCUR can have side effects, like all medicines. For further information about any of these effects, ask a doctor or pharmacist.

If any of the side effects get serious, or if you notice any side effects not listed here, please tell your doctor or pharmacist.

Very frequent side effects:

- Reduced sexual interest (decreased libido)
- Swelling of the breast, breast soreness (gynecomastia)
- Impotence
- Abnormal sperm, low sperm count which may be reversible after ANDROCUR is discontinued.

Other side effects:

- Hair loss or unusual increase in hair growth
- Constipation or diarrhea (loose stools)
- Weight gain
- Tiredness and weakness
- Shortness of breath
- Skin rash, blisters
- Vision change
- Decrease in blood pressure
- Increase in blood sugar
- Depression
- Pulmonary oil microembolism with symptoms such as cough, shortness of breath (dyspnea), or chest pain
- General postinjection reactions (vasovagal reactions) with symptoms such as malaise, increased sweating (hyperhidrosis), dizziness, "pins and needles" (parasthesia) or fainting (syncope)

Rare but serious side effects:

- Liver toxicity: generally feeling unwell, fever, nausea, vomiting, loss of appetite, itching, yellowing of the skin and eyes, light-colored stools, dark-colored urine
- Life-threatening internal bleeding (intra-abdominal hemorrhage): unusual upper abdominal pains which do not disappear within a short time
- Blood clots: swelling of the calf or leg (blood clots in the leg), chest pain and being short of breath (blood clots in the lung), suddenly feeling weak, loss of coordination, slurred speech (a stroke or blood clots in the brain), temporary blindness (blood clots in the eye)

Bone loss (osteoporosis) and benign brain tumors (cerebral meningioma) have been reported with long term use of ANDROCUR.

SERIOUS SIDE EFFECTS, AND WHAT TO DO ABOUT THEM

Symptom/ Effect	Talk with your doctor or pharmacist		Stop taking drug and call your doctor or pharmacist
	Only if severe	In all cases	
Inability to achieve or maintain an erection	✓		
Liver toxicity, (generally feeling unwell, fever, nausea, vomiting, loss of appetite, itching all over the body, yellowing of the skin or eyes, light colored bowel movements, dark urine) liver inflammation (hepatitis), liver failure			✓
Reduced sexual drive	✓		
Reversible inhibition of sperm production	✓		
Swelling of the calf or leg, chest pain, suddenly feeling weak			✓
Unusual upper abdominal pains which do not disappear within a short time			✓

This is not a complete list of side effects. For any unexpected effects while taking ANDROCUR, contact your doctor or pharmacist.

HOW TO STORE IT

Keep out of the reach and sight of children.

Do not take ANDROCUR after the expiry date which is stated on the pack.

Medicines must not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicine no longer required. These measures will help to protect the environment.

REPORTING SUSPECTED SIDE EFFECTS

Canada Vigilance Program

You can report any suspected adverse reactions associated with the use of health products to the Canada Vigilance Program by 1 of the following 3 ways:

- Report online at www.healthcanada.gc.ca/medeffect
- Call toll-free at 1-866-234-2345
- Complete a Canada Vigilance Report Form and:
 - Fax toll free to 1-866-678-6789
 - Mail to: Canada Vigilance Program
Health Canada
Postal Locator 0701D
Ottawa, ON K1A 0K9

Postage paid labels, Canada Vigilance Report Form and the adverse reaction reporting guidelines are available on the MedEffect™ Canada website at www.Healthcanada.gc.ca/medeffect.

NOTE: Should you require information related to the management of the side effect, please contact your health professional. The Canada Vigilance Program does not provide medical advice.

MORE INFORMATION

For more information, please contact your health professional or pharmacist first, or Bayer Medical Information at 1-800-265-7382 or canada.medinfo@bayer.com.

This document plus the full product monograph, prepared for health professionals can be found at <http://www.bayer.ca> or by contacting the manufacturer at the above-mentioned phone number and email address.

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