

Package leaflet: Information for the patient
ANDROPEN ® 375 mg/ml solution for injection
(testosterone ester)

Read all of this leaflet carefully
before you start taking this medicine because it contains
important information for you.

- Keep this leaflet. You may need to read it again.
- If you have further questions, ask your doctor or your pharmacist.
- This medicine has been prescribed for you only. Do not pass it onto others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet.

What is in this leaflet

1. What Andropen is and what it is used for
2. What you need to know before you take Andropen
3. How to take Andropen
4. Possible side effects
5. How to store Andropen
6. Other information

1. WHAT ANDROPEN IS AND WHAT IT IS USED FOR

Composition: Each milliliter of the oily solution contains the following
testosterone acetate 40 mg
testosterone phenylpropionate 65 mg
testosterone propionate 65 mg
testosterone cypionate 95mg
testosterone decanoate 110 mg

The other ingredients are: The solution for injection contains Arachis oil and Benzyl Alcohol.

Form of the drug: Clear oil solution from slightly yellow to yellow colour with characteristic smell

Pharmacological properties: Andropen consists of five Testosterone esters (Acetate, Phenylpropionate, Propionate, Cypionate, Decanoate)

The testosterone is the main sex hormone which is synthesized and secreted by the testis. It stimulates the growth and the

development of the male reproductive organs and secondary sexual characteristics (prostate maturation, seminal vesicles, the penis and the scrotum) It stimulates the production of erythropoietin and red blood cells. The negative side is that it suppresses spermatogenesis.

Women- Inhibits gonadotrophin, Function of the pituitary gland, the functions of the ovaries.

There is beneficial effect during the Climacteric complaints.

Pharmacokinetic properties: The esters in Multi Test have different absorption rates and excretion. So there is excellent effect (4 weeks) after the injection. The effect of Testosterone phenylpropionate and Testosterone propionate starts 24 hours after the injection and lasts up to 2 weeks. The effect of Testosterone decanoate starts later. Biotransformation is in the liver. (6% is in the stools).

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE ANDROPEN

Indications: Men - Androgen deficiency after Impotence, Hormonal imbalance, Decreased libido, Prostate hypertrophy, Osteoporosis
Women - breast cancer, Osteoporosis,

Uterine fibroids, Endometriosis

3. HOW TO TAKE ANDROPEN

Dosage and How to Take It: This medicine is given intramuscularly as directed by your pharmacist. It should not be administered intravenously. Intramuscular injections should be given deep in the gluteal muscle. The dose depends from the patients, the disease state, sex, Clinical effectiveness. Male infertility: 2 ml once every two weeks (Resolving a painful erection). Women with breast cancer : 1-2 ml every 1-2 weeks (Prolonged treatment).
IT SHOULD NOT BE GIVEN INTRAVENOUSLY!

4. POSSIBLE SIDE EFFECTS

Side effects: Priapizym, adults - prostate cancer, Hypertrophy, Frequent erection, Penis enlargement, Little ejaculation, Problems with the prostate gland, Reduction of spermogenesis, Accelerates sexual maturation
Women: virilizing symptoms, change in the menstrual period, inhibition of ovarian function Hypercalcemia

It is possible to has pain, itching and redness at the injection site.
Patients should be instructed to report any of the following: nausea, vomiting, changes in skin color, ankle swelling, too frequent or persistent erections of the penis.

Contraindications: Oversensitivity to the steroids, prostate cancer, breast cancer, atherosclerosis, kidney failure, pregnancy, Breastfeeding, Nephrotic syndrome, Cardiac and coronary insufficiency

Overdose: Overdose may develop Priapism. In this case we should stop the treatment and then start with lower dose.

Preventive measures: When there are androgen-dependent unwanted reactions we

should stop the treatment with testosterone and then start with lower dose.
Patients with latent or apparent heart failure, renal dysfunction, high blood pressure, Epilepsy or migraine are under constant surveillance. Patients with breast cancer, Lung cancer with bone metastases – check the level of calcium in the blood and urine
Boys in puberty – use the Androgens with caution.

5. HOW TO STORE ANDROPEN

It should be stored in a dry place away from heat and humidity. 15° to 25° C (59° to 77° F)

Keep Andropen out of the reach of children and away from pets. Do not refrigerate or freeze;

Store in the original package in order to protect from light
Do not throw away any medicines via wastewater or household waste. Ask your Pharmacist how to throw away medicines you no longer use. These measures will help to protect the environment.

6. OTHER INFORMATION

Expiry date: 5 years. Do not use after the expiry date stated on the pack.

Terms of Use By doctor's prescription

MARKETING AUTHORISATION HOLDER MANUFACTURER:

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Steinbach, MB R5G 0B8 Canada

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