

Package leaflet: Information for the patient

HALOTESTIN® 10 miligrams Tablets

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

1. WHAT HALOTESTIN IS AND WHAT IT IS USED FOR

Composition:

One tablet contains: Fluoxymesterone 10 mg.
Other Ingredients: Magnesium stearate, FD & C ludipress (lactose, povidone, crospovidone).

Form of the drug:

Round tablets of 10 mg with white color and flat surface

Pharmacological properties:

Fluoxymesterone is an androgenic hormone. 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 increases the nitrogen balance in the blood and synthesis of amino acids. The use of Fluoxymesterone before puberty leads to a pineal gland. It increases the erythropoietin in the blood and stimulates the production of erythrocytes. It is possible to suppress the spermatogenesis when we

take high doses. Women with climacteric have a positive effect

Pharmacokinetic properties:

Halotestin binds in the blood with about 98% of plasma proteins. Biotransformation occurs in the liver to 17-ketosteroid with glucuronic acid or sulfuric acid s discarded via the urine. (about 90%)

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE HALOTESTIN

Indications:

Men - Hormone replacement therapy for diseases caused by testosterone deficiency:

- eunuchoidism,
- Impotence
- Hypopituitarism;
- Male climax symptoms (decreased libido, physical and intellectual activity);
- Osteoporosis caused by androgen deficiency.

Women:

- breast cancer;
- Swollen breasts in the postpartum period.

3. HOW TO TAKE HALOTESTIN

Dosage and How to Take It

Young boys and women: Assisting sexual maturation. Boys: 2,5-20 mg / for a day for 4-6 months. Adults: Men: Hypogonadism - 5-20 mg for a day.

Women: Breast cancer: 10-40 mg / day in several doses for 1-3 months.
Swollen breasts in the postpartum period: 2.5 mg after birth, and then 5-10 mg / day in several doses for 4-5 days.

4. POSSIBLE SIDE EFFECTS

Side effects:

- Priapizym and other symptoms of sexual hyperstimulation (frequent erections)
- Accelerated sexual development; Increased erectile dysfunction, penile enlargement, premature eyelid closure;
- Disease affecting spermatogenesis and maturation of sperm
- Prostate disorders;

Women - Bleeding from sexual pathways, increased libido. When we use it for a long period it is possible to appear symptoms of viralisation.

- Hirsutism, gynecomastia;
- Seborrhea, acne, oily skin, hair loss;
- Symptoms of hypercalcaemia;
- Nausea, cholestatic jaundice, elevated liver transaminases (normalize after discontinuation)
- Headache, depression, aggression, anxiety, sleep disturbances.

Contraindications:

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

Overdose:

It is possible to develop priapism. In this case we should stop the treatment and then to continue with lower doses.

Warnings and special precautions for use

In case of side effects we should stop the treatment and then to continue with lower doses. Long-term treatment the liver function must be under supervision. Androgens in pre-

puberty should be taken with caution to avoid stopping growth and premature puberty

Interactions with other medicines:

Fluoxymesterone increases the effectiveness of antidiabetic agents and anticoagulants (it is necessary to correct the dose). Hepatic enzyme inducers (Barbiturates, rifampicin, carbamazepine, phenylbutazone, phenytoin) reduce the effect.

5. HOW TO STORE HALOTESTIN

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

Expiration date: 3 years. Do not use after expiry date.

Terms of Use: By doctor's prescription

MARKETING AUTHORISATION HOLDER MANUFACTURER:

Canadian Pharmaceuticals 32 Tower Ave
Steinbach, MB R5G 0B8 Canada

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