

*Editor's note: This English translation was done by a third party. The original letter can be accessed [here](#).*

## **Ministry of Health of the Republic of Belarus**

### **Order of the Ministry of Health**

#### **Instructions for the medical use of the medicinal product Finasteride-MIC**

Trade name: Finasteride-MIC

International non-proprietary name: finasteride / finasteride Dosage form: coated tablets

Composition: one tablet contains finasteride 5 mg

Excipients: lactose monohydrate, starch, povidone 25, sodium croscarmellose, magnesium stearate, microcrystalline cellulose, hypromellose (hydroxypropyl cellulose), propyl glycol, titanium dioxide (E 171), polysorbate 80, talc, polyethylene glycol 6000 (macrogol 6000), Ponceau dye 4K (E 124).

Description: Round-shaped, film-coated tablets, reddish-pink in color, the upper and lower surfaces of which are convex. The break shows the core, surrounded by one continuous layer.

Pharmacotherapeutic group: Agents for the treatment of urological diseases. Agents for the treatment of benign prostatic hyperplasia. Testosterone 5-alpha reductase inhibitors. ATX code O04CB01.

#### Pharmacodynamics

Finasteride is a competitive inhibitor of human 5-a-reductase, an intracellular enzyme that metabolizes testosterone to the more potent androgen dihydrotestosterone (DHT). In benign prostatic hyperplasia (BPH), prostate enlargement depends on the conversion of testosterone to DHT within the prostate gland. Finasteride effectively reduces the concentration of DHT in the blood and prostate tissues. Finasteride has no affinity for androgen receptors...

#### **Precautions**

##### Mood changes and depression

Mood changes, including depressed mood, depression and, less commonly, suicidal thoughts have been reported in patients taking finasteride. Patients should be evaluated for psychiatric disorders and, if they occur, the patient should seek medical help.

##### Adverse reactions

The most common adverse reactions are impotence and decreased libido. These adverse reactions occur early in therapy and resolve with continued treatment in most patients. Adverse reactions noted during clinical trials and/or post-marketing use are listed in the table. The frequency of adverse reactions that may occur during therapy is given as the following gradation: very often (> 1/10), often (> 1/100, <1/10), infrequently (> 1/1000, <1 /100), rarely (>1/10000, <1/1000), very rarely (<1/10000), unspecified frequency (frequency cannot be calculated from the available data), including individual messages.

Class of organ systems	Frequency of disorder
Immune System Disorders	Frequency unknown: hypersensitivity reactions, including swelling of the lips, tongue, throat and face.
Mental disorders	Often: decreased libido.  Frequency unknown: decreased libido that persists after discontinuation of therapy, depression, anxiety.
Cardiovascular disorders	Frequency unknown: palpitations.
Hepatobiliary system disorders	Frequency unknown: Increased liver enzymes.
Skin and subcutaneous tissue disorders	Uncommon: rash.  Frequency unknown: itching, urticaria.
Reproductive system and breast disorders	Often: impotence.  Uncommon: Ejaculation disorders, breast tenderness, breast enlargement.  Frequency unknown: testicular pain, sexual dysfunction (erectile dysfunction and ejaculation disorders) that may persist after treatment is stopped, male infertility and/or deterioration in the quality of seminal fluid. Normalization or improvement in the quality of seminal fluid was noted after stopping finasteride.
Laboratory research	Often: a decrease in the volume of ejaculate.