Editor's note: This English translation was done by a third party. The original report can be accessed here.

MINISTRY OF HEALTH
OF THE RUSSIAN FEDERATION
(MINZDRAV OF RUSSIA)

3/25 Rakhmanovsky Per, Bldg. 1,2,3,4,
GSP-4, 127994, Moscow
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Applicants for Registration and
Drug Manufacturers of the medicine
containing finasteride as an
active ingredient

10/02/2017 No. 20-3/1582
to No. 2110905 from 09/22/2017

In connection with the letter from the Federal State Budgetary Institution "Scientific Centre for Expert Evaluation of Medicinal Products" of the Minzdrav of Russia dated September 22, 2017 No. 2108054, the Ministry of Health of the Russian Federation informs you that it is necessary to make changes to the instructions for use of medicinal products registered in the Russian Federation for medical use containing finasteride as an active ingredient, according to updated information on experience based on their clinical application.

Appendix: letter of the FSBI "Scientific Centre for Expert Evaluation of Medicinal Products" of the Minzdrav of Russia dated September 22, 2017 No. 2108054, on page 1.

Department Director for
State Regulation of The
Circulation of Medicines *Signature* A. G.
Tsyndymeev
Ryabkova A. S.

(495) 627 24 00, ext. 20-37

MINISTRY OF HEALTH
OF THE RUSSIAN FEDERATION
(Minzdrav of Russia)

**Federal State Budgetary Institution "Scientific Centre for Expert Evaluation of Medicinal Products"
(FSBI "SCEEMP" of the Minzdrav of Russia)**

8 Petrovsky Boulevard., Bldg. 2, 127051, Moscow
tel.: (495) 234-6106, 625-4342; fax: 625-4350

To the Department Director for State Regulation of The Circulation of Medicines of the Ministry of Health of the Russian Federation

A. G. Tsyndymeev

3 Rakhmanovsky per, GSP-4, 127994, Moscow

09/21/2017 No. 18361
to No. ___ from _____
Informational Letter

Minzdrav of Russia
2108054 09/22/17

Dear Arsalan Garmayevich,

In the course of preparing requirements for the safety and efficiency of medicine based on modern evidence-based information on the experience of the clinical use of medicine containing finasteride as an active substance, it was found necessary to supplement the instructions for the use of medicine with the following information.

The following information must be included in the "Special Instructions" section:

"Due to the fact that post-marketing reports of cases of breast cancer in men taking finasteride have been received, the attending physician should immediately report any changes in the patient's breast, such as swelling, enlargement of the mammary glands, discomfort in them, and discharge from the nipple. It is indicated that changes of the mood, including depression and suicidal ideation, were observed in patients taking finasteride at a dose of 5 mg. It is necessary to monitor the appearance of psychopathological symptoms, and when they take place, the patient should be referred for consultation with a specialist."

We consider it appropriate to bring the instructions for usage of medical products containing finasteride as an active ingredient, registered on the territory of the Russian Federation, in accordance with updated information on the experience of their clinical use.

Sincerely,

Deputy General Director
for the Medical Products Examination *Signature* V.A. Merkulov

Goryachev D.V.
(495) 234-61-04