Gesundheitstadt Berlin
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Red Hand Letter: 'Men should be aware of the risks of finasteride'

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

In Germany, thousands of men are taking medicines that contain finasteride. The manufacturers issued a warning in the Red Hand Letter, stating the active substance finasteride can lead to depression and erectile dysfunction. Doctors should warn men, point out the risks and report suspected cases immediately, the warning states.

Finasteride is an active ingredient used to treat hair loss and enlarged prostate, called benign prostatic hyperplasia (BPH). However, the widely prescribed medication can cause serious side effects: Since its launch in the market, many men taking the drug have suffered from depression, anxiety and sexual dysfunction.

More hair on the head, thanks to finasteride. But often with heavy side effects.

Around two dozen manufacturers of finasteride-containing medicines have written a Red Hand Letter to doctors, in cooperation with BfArM. They warn of the side effects and direct doctors to inform their patients about the risks.

Side effects even after discontinuation of therapy

Patients should be aware of the risk of sexual dysfunction, including erectile dysfunction, ejaculation disorder, and decreased libido during finasteride therapy. In addition, manufacturers are calling on physicians to inform their patients that sexual dysfunction may persist 10 years or more after discontinuation of therapy.

Depression and anxiety are now included in the leaflet

The second warning refers to the increased risk of mood swings, depression and suicidal thoughts that can occur with the use of finasteride. The European Medicines Agency (EMA) has decided to include "anxiety" as a new side effect in the information and leaflet for finasteride. In addition, the reference to "depressive mood" had been changed to "depression." If a patient develops such psychiatric symptoms with a dosage of finasteride below 1 mg, it is advised to stop the treatment.

Finally, the manufacturers request physicians to report immediately any suspected case to the authorization holder, or the Federal Institute for Drugs and Medical Devices (BfArM).

Finasteride is an active substance in the group of 5-alpha reductase inhibitors approved in the 1mg dosage since 1998 for the treatment of androgenetic alopecia (hair loss) and in the 5mg dosage since 1994 for the treatment of benign prostatic hyperplasia in Germany. After the approvals, the side effects described here turned out to be a bigger problem.