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

Belgian Federal Agency for Medicines and Health Products

Flash VIG-news
FINASTERIDE: risk of depression
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New data, analyzed by the European Medicines Agency (EMA), has concluded that the risks of mood disorders, suicidal ideation and depression are possible while taking finasteride at 1 mg/day.

Finasteride (in Belgium: PROSCAR® and "generics") is prescribed for benign prostatic hyperplasia at a daily dose of 5 mg/day. At low doses (1 mg/day), it is sometimes used to treat androgenic alopecia. In Belgium, no medical specialty is authorized to prescribe this dosage for this indication. This off-label use, however, remains possible through custom prescriptions prepared by pharmacists.

The risk of depression is already mentioned in the summary of product characteristics (SPC) and the leaflet for the public of finasteride-based treatments. New data complete this risk profile.

The Pharmacovigilance Risk Assessment Committee (PRAC) recently reviewed data on finasteride at a dosage of 1mg and the risk of depression. Based on reports of depression for which a causal relationship was considered possible, the PRAC decided that depression was also a potential adverse effect of finasteride used in alopecia. Its frequency is unknown (07.2017 – CBIP.)

Treatment with finasteride should be discontinued in the event of any psychiatric symptoms. It is important that patients are informed of these risks, since no leaflet accompanies the custom prescriptions of finasteride at 1mg.