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

AEMPS Monthly Bulletin on Human Medicines

Spanish Medicines Agency and Sanitary Products May 2017

New safety information from the periodic evaluation of pharmacovigilance data

The safety information indicated below will be incorporated into the technical data sheets and leaflets of medicines that contain the active ingredients mentioned. The technical data sheets and leaflets of the medicines can be consulted on the AEMPS website, within the CIMA section: Online Medicines Information Center...

Finasteride and Mood Disorders and Depression

Cases of mood disturbances, including depressed mood, depression and, less frequently, suicidal ideation have been reported in patients treated with finasteride 5 mg. This information will be included in the warning section of the drug's data sheet together with the recommendation to monitor patients for the appearance of psychiatric symptoms and if these occur, instruct them to seek medical advice.