

SEPTEMBER 24, 2021

IMPORTANT DRUG WARNING

Subject: Risk of Sexual Dysfunction with Use of Fluoxetine Tablets, USP 60 mg

Dear Health Care Provider:

The purpose of this letter is to inform you of important safety information for Fluoxetine, a selective serotonin reuptake inhibitor approved for the treatment of:

- Major Depressive Disorder in adult and pediatric patients of 8 to 18 years of age.
- Obsessive Compulsive Disorders in adult and pediatric patients of 7 to 17 years of age.
- Bulimia Nervosa in adult patients.
- Panic Disorder in adult patients.

Please see complete indications, including Limitations of Use in the full prescribing information available at www.fluoxetine60.com.

Risk of Sexual Dysfunction with Use of Fluoxetine

Sexual dysfunction (SD) is a known and previously labeled adverse reaction to selective serotonin reuptake inhibitors and serotonin-norepinephrine reuptake inhibitors (SSRIs and SNRIs). New safety information from post-marketing reports in the FDA Adverse Event Reporting System (FAERS) and medical literature has demonstrated that:

- patients report much higher rates of SD when directly queried about sexual function compared to spontaneous reporting in registration trials, and
- there is a need for improvements in prescriber communication of the risks of SD with patients before or during treatment and about potential contributory factors and potential treatment options and management of SD

FDA has therefore determined that in addition to the ADVERSE REACTIONS section of the prescribing information, these risks should be addressed in WARNINGS AND PRECAUTIONS and PATIENT COUNSELING INFORMATION sections of the label, and in the Medication Guide.

Prescriber Action

Counsel patients about the risks and benefits of FLUOXETINE, including the potential risk of symptoms of sexual dysfunction in both male and female patients.

- Inquire about your patient's sexual function prior to initiation of FLUOXETINE and inquire specifically about changes in sexual function during treatment, because sexual function may not be spontaneously reported.
- When evaluating changes in sexual function, obtaining a detailed history (including timing of symptom onset) is important because sexual symptoms may have other causes, including the underlying psychiatric disorder.
- Discuss potential management strategies to support patients in making informed decisions about treatment.

Reporting Adverse Events

Health care providers and patients are encouraged to report adverse events in patients taking FLUOXETINE to ALMATICA at **1-877-447-7979**. You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch, or call 1-800-FDA-1088.

For additional information you may contact our medical information department at **1-877-447-7979** or visit: www.fluoxetine60.com if you have any questions about the information contained in this letter or the safe and effective use of Fluoxetine.

This letter is not intended as a complete description of the benefits and risks related to the use of Fluoxetine. Please refer to the enclosed full prescribing information and medication guide for further information.

Sincerely,

Med Boutouil

Med Boutouil, MD
Sr Medical Director, US PV
Alvogen Inc

Almatica Pharma LLC
Enclosure(s): Fluoxetine Full Prescribing Information