APOTEX
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September 24, 2021

IMPORTANT DRUG WARNING

Subject:	**Risk of Sexual Dysfunction with Use of Paxil (paroxetine) tablets, Paxil (paroxetine) oral suspension, and Paxil CR (paroxetine) extended-release tablets**

Dear Health Care Provider:

The purpose of this letter is to inform you of important safety information for Paxil (paroxetine) tablets and oral suspension and Paxil CR (paroxetine) extended-release tablets, a selective serotonin reuptake inhibitor approved for the treatment of:

- Major depressive disorder (MDD)
- Panic disorder (PD)
- Social anxiety disorder (SAD)
- Obsessive compulsive disorder (OCD) (Paxil only)
- Generalized anxiety disorder (GAD) (Paxil only)
- Posttraumatic stress disorder (PTSD) (Paxil only)
- Premenstrual dysphoric disorder (PMDD) (Paxil CR only)

Please see complete indications, including Limitations of Use in the full prescribing information available at:

- www1.apotex.com/us/paxil
- www1.apotex.com/us/paxilcr

Risk of Sexual Dysfunction with Use of Paxil or Paxil CR

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.

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Prescriber Action

Counsel patients about the risks and benefits of Paxil or Paxil CR, 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 Paxil or Paxil CR 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 Paxil or Paxil CR to Apotex Corp. at 1-800-706-5575. 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.

You may also contact our medical information department at 1-800-706-5575 if you have any questions about the information contained in this letter or the safe and effective use of Paxil or Paxil CR.

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

Sincerely,

Kiran Krishnan, PhD
Senior Vice President
Global Regulatory and Medical Affairs

Paxil and Paxil CR Full Prescribing Information available at:
www1.apotex.com/us/paxil
www1.apotex.com/us/paxilcr