



**Pfizer Receives Complete Response Letter From FDA For Moderate-To-Severe Vasomotor Symptoms (VMS) Indication For PRISTIQ® (desvenlafaxine) Extended Release Tablets**

NEW YORK, N.Y., September 8 - Pfizer Inc. has received a Complete Response Letter from the U.S. Food and Drug Administration (FDA) on its application for a new indication for PRISTIQ® for the treatment of moderate-to-severe VMS (e.g., hot flashes) associated with menopause.

A Complete Response Letter is a communication from the FDA that informs companies that an application cannot be approved in its present form. Pfizer is evaluating the content of the letter and plans further discussions with the FDA.

PRISTIQ is a selective serotonin and norepinephrine reuptake inhibitor (SNRI) approved in 2008 for the treatment of major depressive disorder (MDD) in adults. The Complete Response Letter does not apply to the use of PRISTIQ for major depressive disorder in adults.

Pfizer continues to develop a range of treatments that help women manage different aspects of their health throughout their lives.

**Important Safety Information About PRISTIQ:**

**Suicidality and Antidepressant Drugs**

**Antidepressants increased the risk compared to placebo of suicidal thinking and behavior (suicidality) in children, teens, and young adults. Depression and certain other psychiatric disorders are themselves associated with increases in the risk of suicide. Patients of all ages who are started on antidepressant therapy should be monitored appropriately and observed closely for clinical worsening,**

**suicidality, or unusual changes in behavior. PRISTIQ is not approved for use in children under 18.**

- People taking MAOIs should not take PRISTIQ.
- All patients taking antidepressants should be observed closely for signs that their condition is getting worse or that they are becoming suicidal. This is very important when an antidepressant is started or when the dose is changed. Patients should be watched for becoming agitated, irritable, hostile, aggressive, impulsive, or restless. These symptoms should be reported to the patient's health care professional right away.
- Tell your health care professional about all prescription and over-the-counter medications you are taking or plan to take, including:
  - Medicines to treat migraines or mood disorders, to avoid a potentially life-threatening condition
  - Aspirin, NSAID pain relievers, or blood thinners because they may increase the risk of bleeding
- PRISTIQ may cause or make some conditions worse, so tell your health care professional about all your medical conditions, including if you:
  - Have high blood pressure. Your blood pressure should be controlled before you start taking PRISTIQ and monitored regularly
  - Have heart problems, high cholesterol or triglyceride levels, or a history of stroke
  - Have glaucoma or increased eye pressure
  - Have kidney or liver problems
  - Have or had bleeding problems
  - Have or had depression, suicidal thoughts or behavior
  - Have or had mania, bipolar disorder, or seizures or

convulsions

- o Have low sodium levels in your blood
- o Are nursing, pregnant, or plan to become pregnant
  
- Discontinuation symptoms may occur when stopping PRISTIQ, especially when therapy is stopped suddenly. Talk to your health care professional before you stop taking or reduce the dose of PRISTIQ.
- Until you see how PRISTIQ affects you, be careful driving a car or operating machinery. Avoid drinking alcohol while taking PRISTIQ.
- Side effects when taking PRISTIQ 50 mg may include nausea, dizziness, sweating, constipation, and decreased appetite.

Please see full prescribing information, including boxed warning and Medication Guide at [www.pristiq.com](http://www.pristiq.com).

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