



August 13, 2019

The U.S. Food and Drug Administration (FDA) review finds no increased risk of prostate cancer with the use of entacapone to treat Parkinson's disease.

A [clinical trial from March 2010](#) suggested a possible increased risk of prostate cancer with entacapone; however, after analysis of additional studies and evaluation of data from the Department of Veterans Affairs health care system, the FDA concludes that entacapone use is NOT associated with an increased risk of prostate cancer.

Entacapone is used to help manage Parkinson's disease by increasing the amount of levodopa that is absorbed across the blood brain barrier. This helps to reduce the end-of-dose 'wearing-off' symptoms that occur when concentrations of levodopa drop below a therapeutic level.

Health care professionals should continue to follow standard prostate cancer screening recommendations for patients (see below recommendations from the USPSTF). Medications that contain entacapone should continue to be used the same way as described in the prescribing information.

The Safety Announcement can be found in its entirety by [visiting the FDA's website](#).

U.S. Preventative Services Final Recommendation Statement for Prostate Cancer Screening:

For men aged 55 to 69 years, the decision to undergo periodic prostate-specific antigen (PSA)-based screening for prostate cancer should be an individual one. Before deciding whether to be screened, men should have an opportunity to discuss the potential benefits and harms of screening with their clinician and to incorporate their values and preferences in the decision. Screening offers a small potential benefit of reducing the chance of death from prostate cancer in some men. However, many men will experience potential harms of screening, including false-positive results that require additional testing and possible prostate biopsy; overdiagnosis and overtreatment; and treatment complications, such as incontinence and erectile dysfunction. In determining whether this service is appropriate in individual cases, patients and clinicians should consider the balance of benefits and harms on the basis of family history, race/ethnicity, comorbid medical conditions, patient values about the benefits and harms of screening and treatment-specific outcomes, and other health needs. Clinicians should not screen men who do not express a preference for screening.

The USPSTF recommends against PSA-based screening for prostate cancer in men 70 years and older.