## Supplemental Approvals

| Generic Name (Trade Nameâ€”Company) | **Uses**/Notes |
|---|---|
| July 31, 2018 | |
| **Enzalutamide** | Astellas Pharma and Pfizer announced FDA approval of enzalutamide for treatment of men with nonmetastatic castration-resistant prostate cancer (CRPC). It is the first and only oral medication FDA approved for both nonmetastatic and metastatic CRPC. |
| ***(Xtandi—Astellas, Pfizer)*** | Enzalutamide was first approved by FDA in 2012 to treat patients with metastatic CRPC who had previously received docetaxel, and in 2014, it was granted approval for chemotherapy-naive men with metastatic CRPC. |
| **Agent has new indication for treatment of nonmetastatic castration-resistant prostate cancer** | The updated label is based on results from the Phase III PROSPER trial, which demonstrated that use of enzalutamide plus androgen deprivation therapy (ADT) significantly reduced the risk of developing metastasis or death compared with ADT alone in men with nonmetastatic CRPC.<br><br>The most common adverse reactions in the clinical trial were asthenic conditions, hot flush, hypertension, dizziness, nausea, and fall. |

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http://aphanet.org/supplemental-approvals/agent-has-new-indication-treatment-nonmetastatic-castration-resistant