

## New Drug Approvals

### Generic Name (Trade Name—Company)

February 27, 2018

### Apalutamide

*(Erleada—Janssen)*

**New treatment approved for prostate cancer using novel clinical trial endpoint**

### Uses/Notes

[FDA approved apalutamide](#) to treat patients with prostate cancer that has not spread but that continues to grow despite treatment with hormone therapy (castration-resistant). It is the first FDA-approved treatment for nonmetastatic, castration-resistant prostate cancer.

Approval was based on clinical trial data showing that the agent decreased the risk of distant metastasis or death by 72% and improved median metastasis-free survival by more than 2 years.

The major efficacy outcome was supported by statistically significant improvements for secondary endpoints, including time to metastasis, progression-free survival, and time to symptomatic progression.

Common adverse effects (in at least 10% of patients in the clinical trial) are fatigue, high blood pressure, rash, diarrhea, nausea, weight loss, joint pain, falls, hot flush, decreased appetite, fractures, and swelling in the limb (peripheral edema). Severe adverse effects include falls, fractures, and seizures.

The recommended apalutamide dose is 240 mg (four 60-mg tablets) administered orally once daily.

### Source URL:

<http://aphadruginfoline.com/new-drug-approvals/new-treatment-approved-prostate-cancer-using-novel-clinical-trial-endpoint>

APhA DrugInfoLine is an official publication of, and is owned and copyrighted by the American Pharmacists Association, the national professional society of pharmacists. Materials in APhA DrugInfoLine do not necessarily represent the policy, recommendations, or endorsement of APhA. The publisher, authors, editors, reviewers, and contributors have taken care to ensure that information contained in APhA DrugInfoLine is accurate and current; however, they shall have no liability to any person or entity with regard to claims, losses, or damages caused or alleged to be caused, directly or indirectly, by use of any information contained in the publication. All decisions about drug therapy must be based on the independent judgment of the clinician. Copyright © 2000–2011, American Pharmacists Association. All rights reserved.