Generic Name:
Apalutamide
Trade Name:
Erleada
Company:
Janssen
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.

Medication Monitor Categories:
New Drug Approvals

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