

**Generic:** apalutamide (FDA approved 2/14/18)

**Company:** Janssen Pharmaceutical Companies

**Agent for:** prostate cancer

**Indications:** Indicated for patients with prostate cancer that has not spread to other parts of the body but continues to grow despite hormone therapy treatment or surgery

**Mechanism of Action:** Erleada blocks the effects of androgens, which can promote growth, on the tumor. It decreases tumor cell proliferation by binding to the receptor. It also increases apoptosis to decrease tumor volume.

**COMPARABLE DRUGS:** Erleada is the first of its class but chemotherapy drug treatments include Taxotere, Jevtana, Emcyt and Zytiga.

#### COST PER MONTH (WAC)

ERLEADA: \$10,920.00

TAXOTERE CONCENTRATE : \$2,302.34

JEVTANA: \$10,477.77

EMCYT (700MG/DAY) : \$2,404.97

ZYTIGA: \$10,232.16

#### ADVANTAGES:

- First FDA-approved treatment for non-metastatic, castration-resistant prostate cancer
- First androgen receptor inhibitor in its new class of drug
- Delays spreading of cancer to other parts of the body

#### DISADVANTAGES:

- Erleada may harm fetuses so men who are sexually active and have a partner who is or may become pregnant need to use a condom during and for 3 months after treatment
- May cause fertility problems in males
- Patient should also receive a gonadotropin-releasing hormone analog concurrently or should have surgery to decrease testosterone in the body; not a single drug treatment

**MOST IMPORTANT RISKS/ADVERSE EVENTS:** Most important adverse risks include falls, fractures and seizures. Erleada may cause bones and muscles to weaken which may result in falls and fractures.

**MOST COMMON ADVERSE EVENTS:** Common side effects include fatigue, high blood pressure, rash, diarrhea, nausea, weight loss, joint pain, hot flush and decreased appetite.

**USUAL DOSAGE:** The usual dosage is 240 mg (4 tablets) once daily. Erleada should be taken at the same time each day. It can be taken with or without food. If a dose is missed, it should be taken as soon as possible and the normal schedule should be returned to on the following day. It should be taken with a gonadotropin-releasing hormone analog during the course of treatment. If patients experience an intolerable side effect or toxicity, the dose can be reduced to 180 mg or 120 mg as determined by the primary care provider.

**PRODUCT:** Each tablet contains 60 mg of apalutamide and is slightly yellow, oblong shaped and has "AR 60" imprinted on one side. It should be stored at room temperature at 20°C to 25°C (68°F to 77°F) in the original package with a desiccant packet to keep the product dry. Keep the product away from light and moisture.

**COMMENTS:** Prostate cancer is the most common form of cancer for males in the U.S. The main type of prostate cancer is adenocarcinomas, which develops from the gland cells. It is diagnosed using ultrasound or MRI. Symptoms usually do not occur in the early stages of prostate cancer but can include frequent urges to urinate, painful urination and difficulty achieving or maintaining an erection. Current treatments include surgery, radiation therapy, hormone therapy and chemotherapy. The five-year survival rate for most men with local or regional prostate cancer is nearly 100%. For those diagnosed with prostate cancer that has spread, the five-year survival rate is 29%. This demonstrates why a drug such as Erleada is important in preventing the spread of prostate cancer and increasing the rate of survival. In clinical trials, patients saw a decreased risk of spreading or death by 72% and an increased time until spreading occurred by a median of two years.