darolutamide

Nubeqa

Pharmaceutical company: Bayer HealthCare Pharmaceuticals

Pharmacologic classification: Antineoplastics
Therapeutic classification: Androgen receptor inhibitors

AVAILABLE FORMS

Tablets: 300 mg

INDICATIONS AND DOSAGES

Adjust-a-dose (all indications): For patients with eGFR 15 to 29 mL/minute/1.73m^2 not on hemodialysis, or with Child-Pugh class B liver impairment, decrease dosage to 300 mg b.i.d. Refer to manufacturer's instructions for toxicity related dosage adjustments.

Non-metastatic castration resistant prostate cancer or metastatic castration-sensitive prostate cancer

Adults: 600 mg PO b.i.d. Continue until disease progression or unacceptable toxicity. Patient should also receive a GnRH agonist or antagonist concurrently or have had a bilateral orchiectomy.

Metastatic castration-sensitive prostate cancer in combination with docetaxel

Adults: 600 mg PO b.i.d. Give first of 6 cycles of docetaxel within 6 weeks after the starting drug. Continue darolutamide until disease progression or unacceptable toxicity, regardless of docetaxel treatment delays, interruptions or discontinuation. Refer to docetaxel prescribing information for further information. Patient should also receive a GnRH agonist or antagonist concurrently or have had a bilateral orchiectomy.

ADVERSE REACTIONS

CNS: asthenia, fatigue.
CV: arrhythmia, ***hemorrhage***, ***HF***, HTN, ***ischemic heart disease***.
GI: constipation, decreased appetite.
GU: hematuria, urinary retention, UTI.
Hematologic: anemia, ***febrile neutropenia***, ***lymphocytopenia***, ***neutropenia***.
Hepatic: increased AST, ALT, and bilirubin levels.
Metabolic: hyperglycemia, ***hypocalcemia,*** weight gain.
Musculoskeletal: fracture, limb pain, pain.
Respiratory: pneumonia.
Skin: rash, eczema, skin exfoliation.
Other: ***sepsis***, spinal cord compression.

INTERACTIONS

Drug-drug. *BCRP substrates (rosuvastatin).* May increase substrate level. Avoid use together, if possible. If used together, monitor more frequently for adverse reactions and consider substrate dose reduction.
Combined P-gp and strong CYP3A4 Inhibitors (eitraconazole). May increase darolutamide level. Monitor for adverse reactions and adjust darolutamide dose as needed.
Combined P-gp and strong or moderate CYP3A4 inducers (rifampicin). May decrease darolutamide level. Avoid use together.
Organic anion transporting polypeptides (OATP) 1B1 and 1B3 substrates (rosuvastatin). May increase OATP1B1 or OATP1B3 substrate level. If used together, monitor more frequently for adverse reactions and consider substrate dose reduction.

CONTRAINDICATIONS AND CAUTIONS

- Use cautiously in patients with seizures, or kidney or liver impairment. Use in

patients with eGFR 15 mL/minute/1.73m^2 or less, or Child class C liver impairment haven't been established.
- Drug may cause seizures. It is unknown whether anti-epileptic medications will prevent seizures in patients taking drug.
- Use cautiously in those with CV risk factors (HTN, diabetes, or dyslipidemia). Drug may cause ischemic heart disease.
- Safety and effectiveness in women and children haven't been established.
- ***Dialyzable drug:*** Unknown.

PREGNANCY-LACTATION-REPRODUCTION

- Drug may cause fetal harm and pregnancy loss. Drug isn't indicated for use in females.
- Males with female partners of childbearing potential should use effective contraception during therapy and for 1 week after final dose.
- Drug may impair male fertility.

Reactions in bold italics are ***life-threatening.***

Released: October 2025