

# NUBEQA® PILL SIZE



**Darolutamide**  
tablet



**Apalutamide**  
tablet



**Enzalutamide**  
capsule



For illustrative purposes and pill size comparison only. Sizes accurate as of October 2020. Not intended to compare efficacy, safety, ease of use, adherence, or convenience.

## INDICATION

NUBEQA® (darolutamide) is an androgen receptor inhibitor indicated for the treatment of patients with non-metastatic castration-resistant prostate cancer.

## IMPORTANT SAFETY INFORMATION

**Embryo-Fetal Toxicity:** Safety and efficacy of NUBEQA have not been established in females. NUBEQA can cause fetal harm and loss of pregnancy. Advise males with female partners of reproductive potential to use effective contraception during treatment with NUBEQA and for 1 week after the last dose.

### Adverse Reactions

Serious adverse reactions occurred in 25% of patients receiving NUBEQA and in 20% of patients receiving placebo. Serious adverse reactions in  $\geq 1\%$  of patients who received NUBEQA were urinary retention, pneumonia, and hematuria. Overall, 3.9% of patients receiving NUBEQA and 3.2% of patients receiving placebo died from adverse reactions, which included death (0.4%), cardiac failure (0.3%), cardiac arrest (0.2%), general physical health deterioration (0.2%), and pulmonary embolism (0.2%) for NUBEQA.

Adverse reactions occurring more frequently in the NUBEQA arm ( $\geq 2\%$  over placebo) were fatigue (16% vs 11%), pain in extremity (6% vs 3%) and rash (3% vs 1%).

Clinically significant adverse reactions occurring in  $\geq 2\%$  of patients treated with NUBEQA included ischemic heart disease (4.0% vs 3.4% on placebo) and heart failure (2.1% vs 0.9% on placebo).

Please see additional Important Safety Information on the following page and full [Prescribing Information](#).

**NUBEQA**  
(darolutamide) 300 mg tablets

## NUBEQA: Recommended dosage<sup>1</sup>

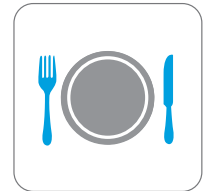
- Two 300 mg tablets administered twice daily with food for a total daily dose of 1200 mg
  - Swallow tablets whole with food
  - Patients should also receive a GnRH analog concurrently or have had a bilateral orchiectomy
- Advise patients to take a missed dose when they remember prior to the next scheduled dose, and not to take 2 doses together to make up for a missed dose



ORAL



TWICE-DAILY



WITH FOOD

GnRH=gonadotropin-releasing hormone.

## Modify dose to 300 mg twice daily in patients with<sup>1</sup>:

- Severe renal impairment (eGFR 15-29 mL/min/1.73 m<sup>2</sup>) not receiving hemodialysis
- Moderate hepatic impairment (Child-Pugh Class B)
- Grade ≥3 toxicity or an intolerable adverse reaction
  - Withhold dose or reduce to 300 mg twice daily until symptoms improve. Then increase to 600 mg twice daily
  - Dosage below 300 mg twice daily is not recommended

For more information, contact your sales representative or visit [NUBEQAhcp.com](http://NUBEQAhcp.com)

## IMPORTANT SAFETY INFORMATION (cont'd)

### Drug Interactions

**Effect of Other Drugs on NUBEQA** – Combined P-gp and strong or moderate CYP3A4 inducers decrease NUBEQA exposure, which may decrease NUBEQA activity. Avoid concomitant use.

Combined P-gp and strong CYP3A4 inhibitors increase NUBEQA exposure, which may increase the risk of NUBEQA adverse reactions. Monitor more frequently and modify NUBEQA dose as needed.

**Effects of NUBEQA on Other Drugs** – NUBEQA inhibits breast cancer resistance protein (BCRP) transporter. Concomitant use increases exposure (AUC) and maximal concentration of BCRP substrates, which may increase the risk of BCRP substrate-related toxicities. Avoid concomitant use where possible. If used together, monitor more frequently for adverse reactions, and consider dose reduction of the BCRP substrate.

NUBEQA inhibits OATP1B1 and OATP1B3 transporters. Concomitant use may increase plasma concentrations of OATP1B1 or OATP1B3 substrates. Monitor more frequently for adverse reactions and consider dose reduction of these substrates.

Review the prescribing information of drugs that are BCRP, OATP1B1, and OATP1B3 substrates when used concomitantly with NUBEQA.

**Please see additional Important Safety Information on the previous page and full [Prescribing Information](#).**

**Reference: 1.** NUBEQA (darolutamide) [prescribing information]. Whippany, NJ: Bayer HealthCare Pharmaceuticals Inc.; January 2021.

