IN THE TREATMENT OF ADVANCED PROSTATE CANCER,

WHAT PROBLEMS COULD DRUG-DRUG INTERACTIONS (DDIs) CAUSE FOR YOUR PATIENTS?

Prescribing Information is available on the last page.

Adverse events should be reported. Reporting forms and information can be found at **https://yellowcard.mhra.gov.uk/**. Adverse events should also be reported to Bayer plc on **0118 206 3500 or pvuk@bayer.com**.

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NUBEQA (darolutamide) is indicated for the treatment of adult men with non-metastatic castration-resistant prostate cancer (nmCRPC) who are at high risk of developing metastatic disease, or with metastatic hormone-sensitive prostate cancer (mHSPC) in combination with docetaxel.[1]

Intended for UK healthcare professionals only.

PP-NUB-GB-1906 | February 2025

NUBEQA® (darolutamide) 300 mg tablets

In patients with advanced prostate cancer,

THE RISK OF ARI-RELATED DDIs IS AN IMPORTANT CONSIDERATION DURING TREATMENT[2]

66%

of prostate cancer patients are comorbid and take 5 or more comedications[2]

UP TO 85%

of advanced prostate cancer patients are at risk of at least 1 major DDI with enzalutamide[3]

DDIs may cause treatment and/or management complexities:[2,4]

REDUCED EFFICACY
of the ARI and other prescribed medication

DOSE ADJUSTMENT, DISCONTINUATION, OR SWITCHING

INCREASED RISK, INCIDENCE, AND SEVERITY OF AEs

INCREASED STRESS, CONFUSION, AND ANXIETY
for patients and caregivers[4,5]

INCREASED HEALTHCARE BURDEN

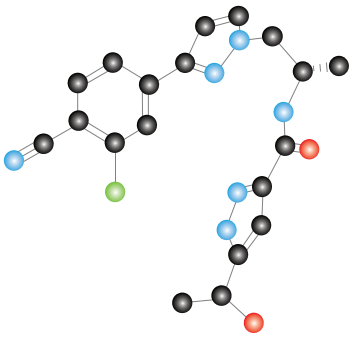
DDIs can create challenges for you, members of the MDT, your patients and their caregivers[2,4]

CONSIDER DDIs BEFORE CHOOSING A THERAPY FOR ADVANCED PROSTATE CANCER

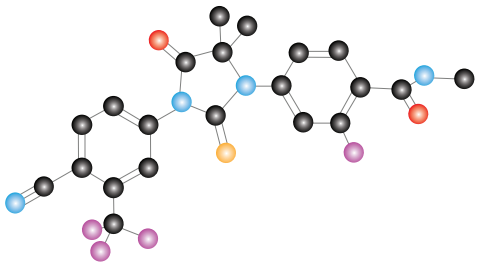
Efficacy that doesn't compromise your patient's QoL. Choose NUBEQA in mHSPC and nmCRPC[1,6-9*]

NUBEQA is different by design. NUBEQA offers a distinct molecular structure and fewer drug-drug interactions vs other second generation ARIs[10-13]

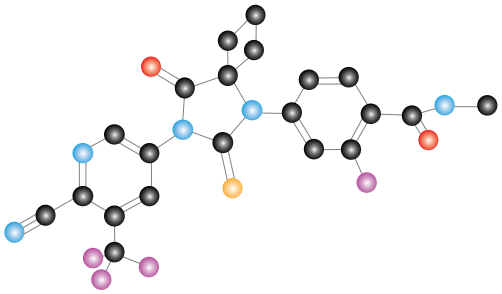
NUBEQA



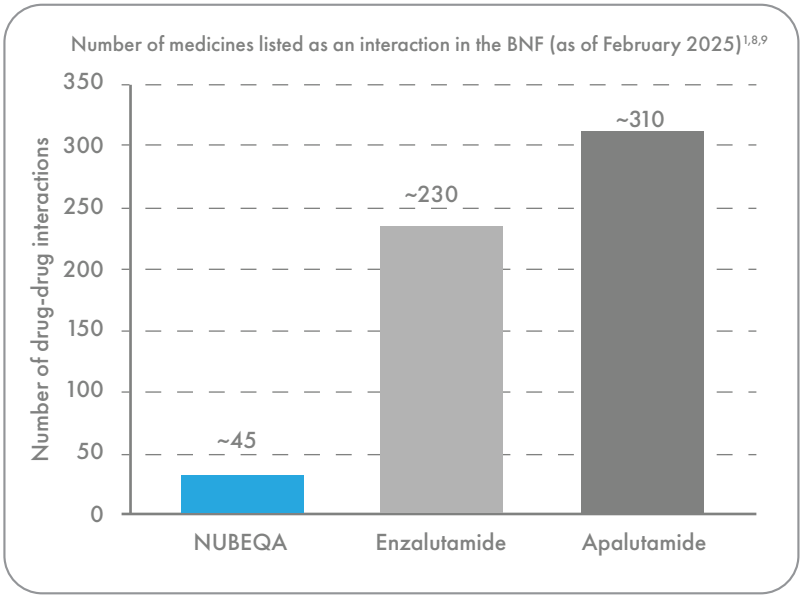
Enzalutamide



Apalutamide



NUBEQA has been shown to interact with fewer medications compared with other second generation ARIs, offering confidence when treating patients receiving concomitant medications[1,8,9]



*The eligibility criteria for treatment with darolutamide for patients with high-risk nmCRPC is: No metastases detected in recent imaging, pelvic lymph nodes <2 cm permissible; Castration-resistant prostate carcinoma at (testosterone <1.7 nmol/L PSA increase while on ADT, PSA ≥2 ng/ml); PSA doubling time of ≤10 months (This list is not exhaustive).[6, 14]

Choosing an ARI with reduced potential for drug-drug interactions can help to ensure your patients can retain their current comorbidity treatments[1,8,9]

Learn more about NUBEQA's mechanism of action

This QR code will take you to a promotional Bayer website.

Efficacy that doesn't compromise your patient's QoL. Choose NUBEQA in mHSPC and nmCRPC[1,6-9*]

Extends

Extended overall survival by

>30%

across **mHSPC** (vs ADT and docetaxel alone) and **nmCRPC** (vs placebo + ADT)[7, 15]

Delays

Delayed tumour progression by

22 months

vs placebo + ADT in **nmCRPC**[6‡]

Maintains QoL

<1%

increase in AE incidence when added to ADT and docetaxel in **mHSPC**[7,16]

The only ARI

The only ARI with

<1%

increase in treatment discontinuation when added to ADT in a Phase 3 clinical trial in **nmCRPC**[6]

NUBEQA is the only NICE-recommended and SMC-accepted therapy in combination with ADT and docetaxel in mHSPC[1,17,18]

The first NICE-recommended and SMC-accepted ARI in high-risk nmCRPC[1,19,20]

EXTEND SURVIVAL.

MAINTAIN YOUR PATIENT'S QoL.[1,6-9] CHOOSE NUBEQA.

LEARN MORE ABOUT NUBEQA

This QR code will take you to a promotional Bayer website.

Prescribing information and adverse event reporting information for NUBEQA (darolutamide) is available via the QR code on the right.

Either click here or scan the QR code for prescribing information and adverse event reporting information.

For direct access to this prescribing information, please ensure your device's browser settings have automatic PDF download enabled.

ARASENS trial. Men with mHSPC. NUBEQA + ADT + docetaxel (n=651) vs. placebo + ADT + docetaxel (n=654). Primary endpoint was OS. 32.5% reduction in risk of death vs. placebo + ADT + docetaxel (HR: 0.68; 95% CI: 0.57-0.80; p<0.001). Median OS: NE months vs. 48.9 months with placebo + ADT + docetaxel. Number of patients with events 229/561 (35.2%) vs. 304/654 (46.5%) with placebo + ADT + docetaxel. Docetaxel 75 mg/m2 q3w x 6 cycles.[7]

ARAMIS trial. Men with high-risk nmCRPC. NUBEQA + ADT (n=955) vs. placebo + ADT (n=554). Primary endpoint was median MFS. Median MFS for NUBEQA + ADT was 40.4 months (n=955) vs. 18.4 months for placebo + ADT (n=554) (HR: 0.41; 95% CI: 0.34–0.50; p<0.001). Secondary endpoint was OS. 31% reduction in risk of death vs ADT alone. OS for NUBEQA + ADT was NR (95% CI: 56.1-NR) vs NR (95% CI: 46.9-NR) for placebo + ADT (HR: 0.69 (95% CI: 0.53-0.88), p=0.003). Number of patients with OS events 148/955 (15.5%) vs. 106/554 (19.1%) with placebo + ADT. Final analysis for OS was conducted after 254 deaths.[6,15]

The most common AEs in **mHSPC** patients receiving NUBEQA in combination with docetaxel were rash (17.3%), ALT increased (15.8%), AST increased (14.0%) and hypertension (13.8%).[1] The most common AE in **nmCRPC** patients receiving NUBEQA was fatigue/asthenic conditions (15.8%).[1] **Please refer to the NUBEQA SmPC for the full safety information.**

‡The eligibility criteria for treatment with darolutamide for patients with high-risk nmCRPC is: no metastases detected in recent imaging, pelvic lymph nodes <2 cm permissible; castration-resistant prostate carcinoma (testosterone <1.7 nmol/L, PSA increase while on ADT, PSA ≥2 ng/mL); PSA doubling time of ≤10 months (this list is not exhaustive).[6,14]

ADT, androgen deprivation therapy; AE, adverse event; ALT, alanine aminotransferase; ARI, androgen receptor inhibitor; AST, aspartate transferase; BNF, British National Formulary; CI, confidence interval; DDI, drug-drug interaction; HR, hazard ratio; mCRPC, metastatic castration-resistant prostate cancer; MDT, multi-disciplinary team; MFS, metasasis-free survival; mHSPC, metastatic hormone-sensitive prostate cancer; NE, not estimable; nmCRPC, non-metastatic castration-resistant prostate cancer; NICE, National Institute of Health and Care Excellence; NR, not reached; OS, overall survival; p, probability; PSA, prostate-specific antigen; QoL, quality of life; q3w, once every 3 weeks; SMC, Scottish Medicines Consortium; SmPC; summary of product characteristics.

1. NUBEQA (darolutamide) Summary of Product Characteristics. 2024. **2.** Appukkuttan S, et al. Expert Rev Anticancer Ther. 2024;24(5)325-333. **3.** Benoist GE, et al. Br J Clin Pharmacol. 2018;84:122-129. **4.** Conde-Estevez D, et al. Exp Op Drug Metab Toxicol. 2022;18(9):601-613. **5.** Morgans AK et al. Clin Genitourin Cancer. 2021;19(5):467-e1. **6.** Fizazi K, et al. N Engl J Med. 2019;380(13):1235-46. **7.** Smith MR, et al. N Engl J Med. 2022;386(12):1132-42. **8.** XTANDI (enzalutamide) Summary of Product Characteristics. 2024. **9.** ERLEADA (apalutamide) Summary of Product Characteristics. 2024. **10.** Heidegger I, et al. Urol Oncol. 2020;38(4):129–36. **11.** Zurth C, et al. J Clin Oncol. 2019;37(Suppl. 7):156. **12.** Williams SCR, et al. Target Oncol. 2023;18(3):403–13. **13.** Cintrón-García J and Guddati AK. Am J Cancer Res. 2020;10(8):2617–20. **14.** Crawford ED. et al. Cancer Manag Res. 2020;12:5667- 5676. **15.** Fizazi K et al. N Engl J Med. 2020;383:1040–1049. **16.** Bayer. Data on file. REF-M_DAR-GB-0641 **17.** NICE. TA903. 2023. **18.** SMC. SMC2604. **19.** NICE. TA660. 2020. **20.** SMC. SMC2297. 2020.

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