HOW DO YOU ASSESS YOUR PATIENTS' RISK OF TREATMENT-RELATED RASH WHEN DETERMINING THEIR PROSTATE CANCER TREATMENT?

Prescribing information is available via the QR code 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-1910 | February 2025

NUBEQA® (darolutamide) 300 mg tablets

RASH IMPACTS PATIENTS PHYSICALLY AND EMOTIONALLY, AND MANAGING IT ADDS COMPLICATIONS[2-5]

PHYSICAL

- Swelling, redness
- Itching, burning, stinging, pain

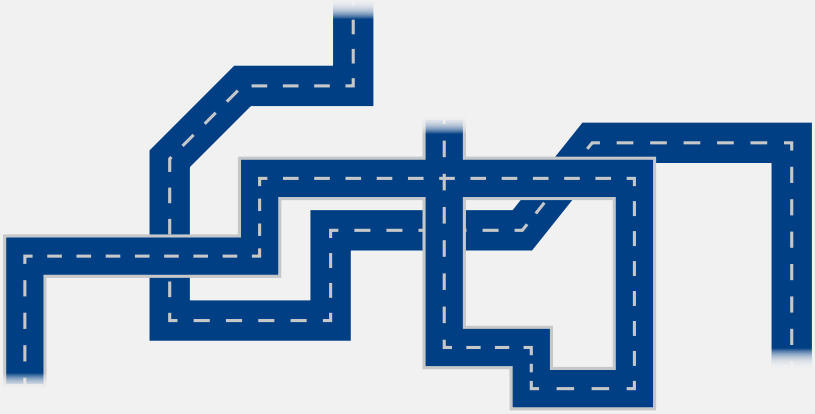
LIFESTYLE CHANGES

- Changes in how patients care for their skin[3]
- Rash can affect patients psychologically, impact their quality of life, and interfere with their daily activities[3-5]

HEALTHCARE BURDEN

- Prostate cancer treatment modification and new drug initiations
- Additional appointments, monitoring and coordination with other HCPs[4]

MANAGING RASH CAN BE COMPLICATED, WITH SEVERAL POSSIBLE PATHS TO FOLLOW[2-4]



Reducing or pausing prostate cancer treatment for varying lengths of time based on severity, potentially impacting efficacy[3]

Careful monitoring over the course of mutliple weeks, including hospital admission in severe cases[3,4]

Prescribing additional treatment (eg, topical steroids, oral steroids, oral antihistamines, etc).[3] In collaboration with dermatologists and other members of the patient's care team[4]

HOW HAS RASH CAUSED BY ARI INITIATION BURDENED YOUR PROSTATE CANCER PATIENTS AND PRACTICE?

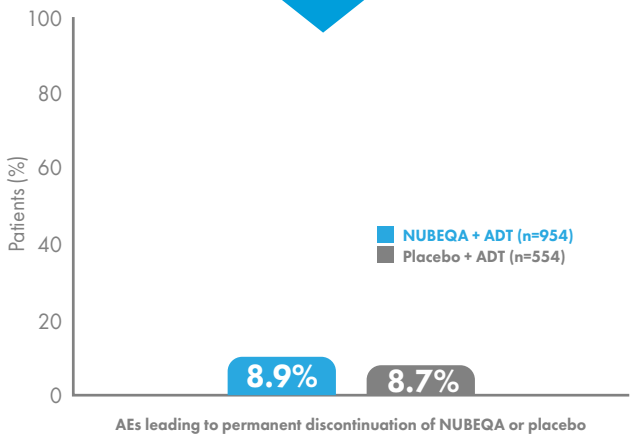
Efficacy that doesn't compromise your patient's QoL. Choose NUBEQA (darolutamide) in mHSPC and nmCRPC[1,6-9*]

INCIDENCE OF RASH WITH NUBEQA VERSUS PLACEBO ACROSS BOTH TRIALS[1,6,7,10†]

ARAMIS (patients with nmCRPC)		ARASENS (patients with mHSPC)		Across NUBEQA trials (nmCRPC and mHSPC)			
Incidence of rash		Incidence of rash		Dose reduction due to rash		Dose interruption due to rash	Discontinuations due to rash
NUBEQA + ADT	Placebo + ADT	NUBEQA + ADT + docetaxel	Placebo + ADT + docetaxel	(nmCRPC)	(mHSPC)	(mHSPC only)	(nmCRPC and mHSPC)
2.9%	0.9%	17.3%	13.7%	0.1%	0.5%	1.4%	1.1%

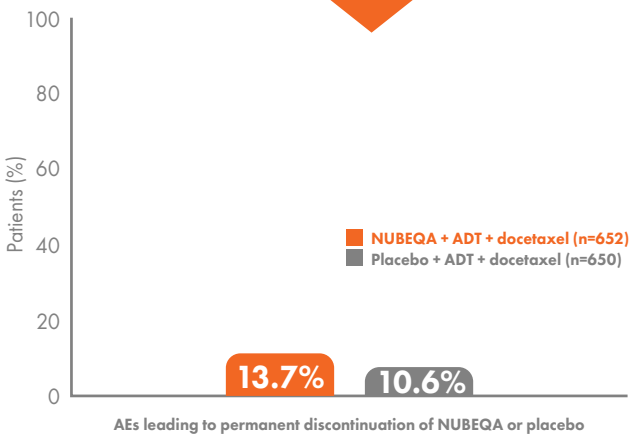
- Stevens-Johnson syndrome was **NOT REPORTED** across NUBEQA trials[1,6,7]

DISCONTINUATION RATES FOR nmCRPC IN ARAMIS TRIAL[6]



Adapted from Fizazi K *et al.* 2019.

DISCONTINUATION RATES FOR mHSPC IN ARASENS TRIAL[7]



Adopted from Smith MR *et al.* 2022.

Learn more about NUBEQA's mechanism of action

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

†ARASENS trial. Men with mHSPC. NUBEQA + ADT + docetaxel (n=651) vs. placebo + ADT + docetaxel (n=654). Primary endpoint was OS. Docetaxel 75 mg/m 2 q3w x 6 cycles.[7]

*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).[6,11]

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)[7,12]

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**[7,10]

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[1,13,14]

The first NICE-recommended and SMC-accepted ARI in high-risk nmCRPC[1,15,16]

EXTEND SURVIVAL.

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

LEARN MORE ABOUT NUBEQA

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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.[6,12]

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).[6,11]

ADT, androgen deprivation therapy; AE, adverse event; ALT, alanine aminotransferase; ARI, androgen receptor inhibitor; AST, aspartate transferase; CI, confidence interval; HCP, healthcare professional; HR, hazard ratio; 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.

References: 1. NUBEQA (darolutamide) Summary of Product Characteristics. 2024. **2.** American Cancer Society. Skin rash. Accessed January, 2025. https://www.cancer.org/cancer/managing-cancer/side-effects/hair-skin-nails/skin-rash.html. **3.** Shore N. et al. Prostate Cancer Prostatic Dis. Published online July 5, 2024. **4.** Birtle AJ et al. Oncology and Therapy. 2024; 12(3), 609-620 **5.** Almeida V et al. Healthcare (Basel). 2023; 11(19):2621 **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.** Bayer. Data on file. REF-M _DAR- GB-0641 **11.** Crawford ED. et al. Cancer Manag Res. 2020;12:566 **12.** Fizazi K et al. N Engl J M ed. 2020;383:1040–1049. **13.** NICE. TA903. 2023. **14.** SMC. SMC2604. **15.** NICE. TA660. 2020. **16.** SMC. SMC2297. 2020.

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