Prescribing information and adverse event reporting for NUBEQA® (darolutamide) can be accessed via the QR code and link located on the last page of this document.

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IS YOUR PATIENT WITH nmCRPC AT RISK OF DEVELOPING METASTASIS?

CHECKLIST FOR PRESCRIBING NUBEQA® (darolutamide), for delaying metastasis and improving overall survival* without impacting upon quality of life, compared to placebo[1,2]

Patients should meet the following criteria:

Adult men with non-metastatic castration resistant prostate cancer (nmCRPC) who are at high risk of developing metastatic disease.**

No metastases detected in recent imaging, pelvic lymph nodes up to 2 cm permissible†	☑
Castration-resistant prostate carcinoma (testosterone <1.7nmol/L PSA increase while on ADT, PSA ≥2 ng/ml)	☑
PSA doubling time of ≤10 months	☑

If your patient meets these criteria, they are at high risk of developing metastatic disease – treat now with NUBEQA (darolutamide), NICE and SMC approved for high-risk nmCRPC.[3,4] Please refer to the Blueteq funding criteria to prescribe NUBEQA for your patients.

If you wish to know more about NUBEQA please visit https://pro.bayer.co.uk/oncology-homepage.

Patients were included in the ARAMIS trial if they had 3 rising prostate-specific antigen (PSA) levels after the nadir taken at least 1 week apart during androgen deprivation therapy, PSA ≥2 ng/mL at screening and castrate level of serum testosterone <1.7 nmol/L.[4]

* Efficacy of the ARAMIS trial showed an increase in metastasis-free survival (HR 0.41; 95% CI, 0.34 to 0.50; P<0.001) and overall survival (HR, 0.69; 95% CI, 0.53 to 0.88; P<0.01) for darolutamide when compared to placebo.[1,2]

** Full details on NUBEQA can be found in the Summary of Product Characteristics, available at: https://www.medicines.org.uk/emc/product/11324.

† Pelvic lymph nodes <2 cm in diameter in the short axis below the aortic bifurcation was allowed in the ARAMIS Phase III trial.

NUBEQA® (darolutamide) 300 mg tablets

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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.

1. NUBEQA (darolutamide) Summary of Product Characteristics. Available https://www.medicines.org.uk/emc/product/11324 (Accessed February 2025).
2. Fizazi K, Shore N, Tammela TL, et al. Nonmetastatic, castration-resistant prostate cancer and survival with Darolutamide. *N Engl J Med.* 2020;383(11):1040–1049.
3. NICE. Darolutamide with androgen deprivation therapy for treating hormone-relapsed nonmetastatic prostate cancer. TA660. 2020. Available at https://www.nice.org.uk/guidance/TA660 (Accessed February 2025).
4. SMC. NUBEQA (darolutamide). Available at: https://www.scottishmedicines.org.uk/medicines-advice/darolutamide-nubeqa-full-smc2297 (Accessed February 2025).

ADT, androgen deprivation therapy; nmCRPC, non-metastatic castration resistant prostate cancer

Bayer plc
400 South Oak Way
Reading, RG2 6AD
Great Britain

PP-NUB-GB-2075 | Feburary 2025

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