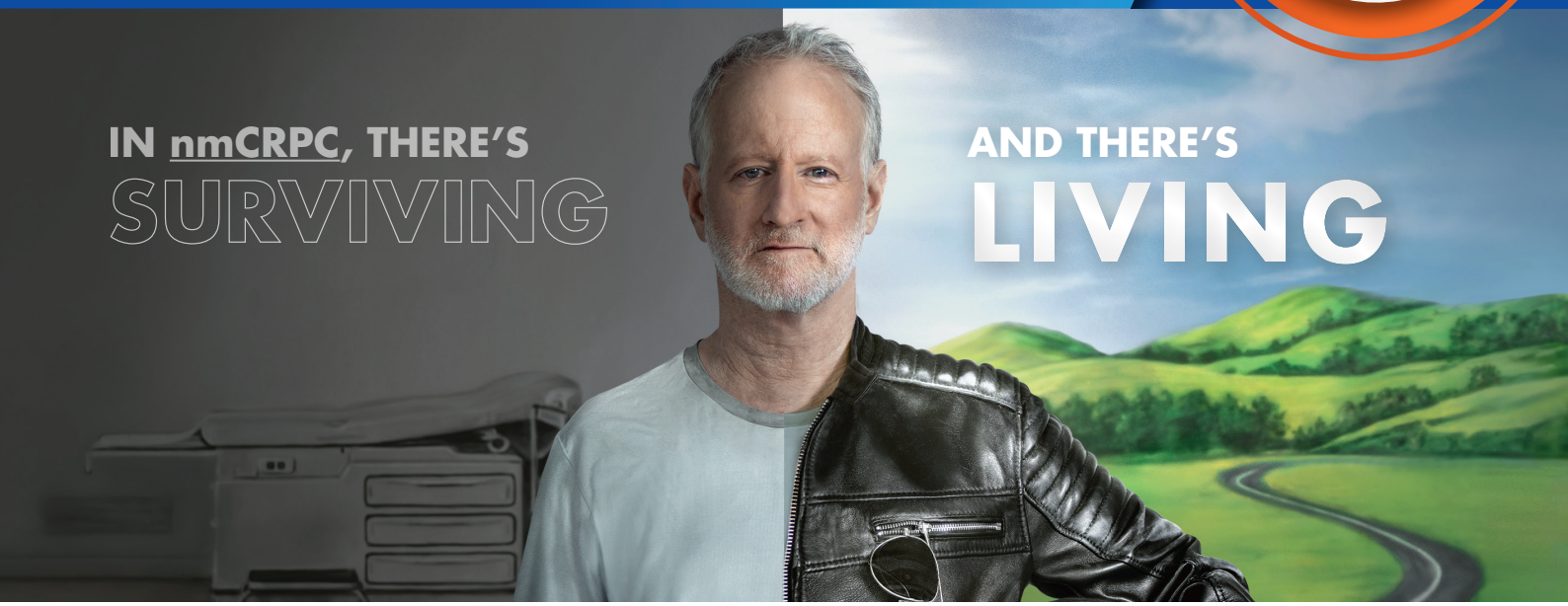
NUBEQA® (darolutamide):

Extend patient's lives without compromising quality of life (QOL):*[2-4]

*In patients with nmCRPC NUBEQA® (darolutamide) + ADT significantly improved overall survival vs ADT alone (HR 0.69, 95% CI 0.53-0.88; p=0.003 [secondary endpoint]); and significantly improved metastasis-free survival vs ADT alone (40.4 vs 18.4 months; HR 0.41, 95% CI 0.34-0.50; p<0.001 [primary endpoint]). Patient QOL was maintained throughout the duration of treatment: Patient-reported QOL was similar in the NUBEQA® + ADT vs ADT alone group; frequency of adverse events and discontinuations were comparable to ADT alone.[2-4]

PBS LISTED for nmCRPC[1]



PBS Information: This product is listed on the PBS. Authority Required (immediate/real-time assessment by Services Australia). Refer to PBS schedule for more information www.pbs.gov.au

NUBEQA®
(darolutamide) 300 mg tablets

Please review Product Information before prescribing. Full Product Information is available at https://www.ebs.tga.gov.au/ebs/picmi/picmirepository.nsf/pdf?OpenAgent&id=CP-2020-PI-01276-1&d or upon request from Bayer Australia Ltd. ABN 22 000 138 714. 875 Pacific Highway, Pymble NSW 2073.

▼This medicinal product is subject to additional monitoring in Australia. This will allow quick identification of new safety information. Healthcare professionals are asked to report any suspected adverse events at www.tga.gov.au/reporting-problems.

MINIMUM PRODUCT INFORMATION NUBEQA® (darolutamide)

INDICATIONS: Nubeqa is indicated for the treatment of patients with non-metastatic castration resistant prostate cancer (nmCRPC). **CONTRAINDICATIONS:** Hypersensitivity to darolutamide or excipients in tablet, women who are or may become pregnant. **PRECAUTIONS:** Cardiovascular events (the safety of darolutamide has not been characterised in patients with recent (within 6 months) cardiovascular events), hepatic impairment, renal impairment. The safety and efficacy in children and adolescents (< 18 years) have not been established. **INTERACTIONS WITH OTHER MEDICINES:** Darolutamide is a substrate of CYP3A4, P-glycoprotein (P-gp) and Breast Cancer Resistance Protein (BCRP). Darolutamide is an inhibitor of BCRP and Organic Anion Transporting Polypeptides (OATP) 1B1 and 1B3 and a weak inducer of CYP3A4. In vitro data indicate darolutamide administration may inhibit OAT3, MATE1, MATE2K and intestinal MRP2. Darolutamide did not inhibit the transporters, BSEP, OAT1, OCTs, OATP2B1 and NTCP at clinically relevant concentrations. Please refer to the full Product Information for more information. **ADVERSE EFFECTS:** The most frequently observed adverse drug reaction (≥ 10%, very common) in patients receiving Nubeqa is fatigue. Common (≥ 1/100 to < 1/10) adverse drug reactions include rash and pain in extremity. Please refer to full Prescribing Information for a complete list of adverse effects and laboratory test abnormalities. **DOSAGE AND ADMINISTRATION:** 600 mg (two film-coated tablets of 300 mg) taken twice daily, equivalent to a total daily dose of 1200 mg. The tablets should be taken whole with food. Patients receiving Nubeqa should also receive a gonadotropin-releasing hormone (GnRH) analogue concurrently or should have had bilateral orchiectomy. In case of toxicity or an intolerable adverse reaction, dosing should be withheld or reduced, for more information see full Prescribing Information. **DATE OF PREPARATION:** November 2021, based on PI dated 08-Nov 2021.

References: 1. Pharmaceutical Benefits Scheme www.pbs.gov.au (accessed November 2021). **2.** NUBEQA® (darolutamide) Approved Product Information. **3.** Fizazi K et al. N Engl J Med 2019;380(13):1235-1246 (including Supplementary Appendix). **4.** Fizazi K et al. N Eng J Med 2020;383:1040-1049.