NUBEQA® (darolutamide) 300 mg tablets

Is it time for NUBEQA?

Mr Tan's story*

NUBEQA 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.[1]

- *Aged 72*
- *Retired electrical engineer*
- *Grandfather to 3 grandkids*
- *Rides the bicycle few times a week to market for grocery shopping*
- *Enjoys 'kopi' at coffeeshop with his neighbours*

Mr Tan* is relieved life doesn't have to change - too much - just yet

"When my doctor told me that my PSA is starting to rise again, I thought "uh oh'. My PSA has been controlled for many years with my current medications. Now at this stage, I am not sure what to expect.

After my doctor spoke to me, I can say that the consultation went better than I had expected.

I am now aware that my prostate cancer has progressed. But my doctor says that he will put me on tablets to keep my cancer in check to slow down the progression, and hopefully without many more side effects than my previous medications. I am glad that there are options to slow down the progression of my cancer."

Mr Tan's medical profile (and history)

TODAY	**Aged 72**	**7 years** since diagnosis
	No lymph nodes on central imaging review	Serum PSA **8.9 ng/mL**
	PSA doubling time **4.6 months**	Serum testosterone **0.7 nmol/L**
	ECOG PS = 0	No use of **bone-sparing agents**
8 MONTHS	**PSA rise** in three separate blood tests	
3 YEARS	**Diagnosis** Undergone prostatectomy Initiated on leuprorelin acetate	

Dr Lee* wants to preserve Mr Tan's QoL – and delay the 'tipping point' into mCRPC

"Mr Tan's clearly entered a castrate-resistant phase, but he's yet to demonstrate visible mets on scans. I'm keen to keep him in this 'pre-metastatic' CR state; to preserve his excellent ECOG score and keep mCRPC (or more aggressive) treatments for later lines.

NUBEQA seems an appropriate choice: compared with ADT alone, it has been shown to delay metastasis and significantly extended overall survival in patients with nmCRPC.[1,3†] It also has an AE profile that Mr Tan should be able to tolerate.[1,2]"

†MFS was 40.4 months (NUBEQA) vs. 18.4 months (placebo, HR= 0.41; 95% CI 0.34-0.50; p<0.0001). Significant OS gains with NUBEQA vs. placebo (HR= 0.69; 95% CI 0.53-0.88; p=0.003). [1,3]

Don't miss the chance to prolong quality time: choose NUBEQA for patients like Mr Tan

*Fictional characters, for illustrative purposes only.

ADT: androgen deprivation therapy; AE: adverse event; CR: castrate resistant; ECOG: Eastern Cooperative Oncology Group; mCRPC: metastatic castrate-resistant prostate cancer; MFS: metastasis-free survival; PS: performance status; PSA: prostate-speci c antigen, QoL: quality of life.

References:

1. NUBEQA® (Darolutamide) Approved Package Insert, Singapore, September 2021. Bayer (South East Asia) Pte Ltd.
2. Fizazi K et al. N Engl J Med. 2019;380(13):1235-1246. **3.** Fizazi K et al. N Engl J Med. 2020;383:1040-1049.

Oncology *Inspired*

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ABBREVIATED PRESCRIBING INFORMATION

Nubeqa® [darolutamide] 300 mg film-coated tablets. Composition each film-coated tablet contains 300 mg of darolutamide. **Indication** Nubeqa 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. **Posology and method of administration** Recommended dose is 600 mg darolutamide (two tablets of 300 mg) taken twice daily, equivalent to a total daily dose of 1200 mg. If a patient experiences a ≥ grade 3 toxicity or an intolerable adverse reaction, dosing should be withheld or reduced to 300 mg twice daily until symptoms improve. Treatment may then be resumed at a dose of 600 mg twice daily. Nubeqa is for oral use and tablets should be taken whole with food. **Contraindications** Hypersensitivity to the active substance or to any of the excipients. Women who are or may become pregnant. **Special warnings and precautions for use** *Renal impairment:* the available data in patients with severe renal impairment are limited. As exposure might be increased those patients should be closely monitored for adverse reactions. *Hepatic impairment:* the available data in patients with moderate hepatic impairment are limited, and darolutamide has not been studied in patients with severe hepatic impairment. As exposure might be increased those patients should be closely monitored for adverse reactions. *Recent cardiovascular disease:* patients with clinically significant disease in the past 6 months, including stroke, myocardial infarction, severe/unstable angina pectoris, coronary/peripheral artery bypass graft, and symptomatic congestive heart failure were excluded from the clinical studies. Therefore the safety of darolutamide in these patients has not been established. *Concomitant use with other medicinal products:* use of strong CYP3A4 and Pgp inducers during treatment with darolutamide may decrease the plasma concentration of darolutamide and is not recommended, unless there is no therapeutic alternative. Selection of an alternate concomitant medicinal product with less potential to induce CYP3A4 or Pgp should be considered. Patients should be monitored for adverse reactions of BCRP, OATP1B1 and OATP1B3 substrates as co-administration with darolutamide may increase the plasma concentration of these substrates. Co-administration with rosuvastatin should be avoided unless there is no therapeutic alternative. *Androgen deprivation therapy may prolong the QT interval:* in patients with a history of risk factors for QT prolongation and in patients receiving concomitant medical products that might prolong the QT interval, physician should assess the benefit-risk ratio including the potential for Torsade de pointes prior to initiating Nubeqa. *Information about excipients:* Nubeqa contains lactose. Patients with rare hereditary problems of galactose intolerance, total lactase deficiency or glucose-galactose malabsorption should not take this medicinal product. **Undesirable effects** *Very common* fatigue/asthenic conditions, neutrophil count decreased, billirubin increased and AST increased; *Common:* ischaemic heart disease, heart failure, rash, pain in extremity, musculoskeletal pain and fractures. For a full listing of undesirable effects, please refer to the full product insert. **For full prescribing information, please contact:** Bayer (South East Asia) Pte. Ltd. 2, Tanjong Katong Road #07-01, Paya Lebar Quarter 3, Singapore 437161. **Date of revision text:** June 2020.

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Full prescribing information is available on request