ONCOASSIST®

A PSA-DT calculator for high risk nmCRPC patient identification.

NUBEQA® (darolutamide) 300 mg tablets

nmCRPC patients should meet the following criteria for NUBEQA® (darolutamide) initiation

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.

CHECKLIST for prescribing NUBEQA® for delaying metastasis and extending overall survival with minimal disruption* to men´s daily lives[1,2]

- No metastases detected using conventional imaging (CT, bone scan or MRI images), pelvic lymph nodes up to 2 cm permissible**
- Castration-resistant prostate carcinoma (testosterone < 1,7 nmol/L (50 ng/dl) PSA increase while on ADT, PSA ≥ 2 ng/ml)
- PSA doubling time of ≤ 10 months

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.[1,2]

*Median MFS: 40,4 months with NUBEQA + ADT vs 18,4 months ADT alone HR: 0,41 (95 % CI, 0,34–0,50) P < 0,001; Median OS: NR with NUBEQA + ADT and NR with ADT HR: 0,69 (95 % CI, 0,53–0,88) P = 0,0034; Discontinuation due to AEs was 8,9 % with NUBEQA + ADT vs. 8,7 % with ADT.[1,2]

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

ADT, androgen deprivation therapy; nmCRPC, non-metastatic castration resistant prostate cancer; PSA, prostate specific antigen.

1. NUBEQA® (darolutamide) SPC, 10/2020.

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.

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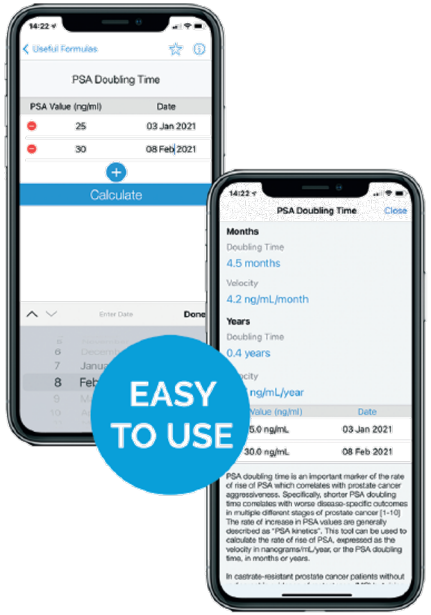
ONCOAssist provides an opportunity to calculate the PSA doubling time and includes many other additional tools to support HCPs

- ONCOAssist is the free go-to app for Oncology Healthcare Professionals
- Provides access to relevant tools and information needed at the point of care, thus supporting HCPs in their decision-making process
- Download the app from **AppStore** or **Google Play** store to calculate the PSA doubling time or go to www.oncoassist.com

Already have ONCOAssist? Go straight to PSA calculator by scanning here

Scan here to download the ONCOAssist app



ONCOASSIST® includes:

- ✓ PSA doubling time calculator
- ✓ Drug interaction checker
- ✓AJCC staging tool (7th and 8th edition) that provides easy access to the full library of AJCC criteria for every malignancy
- ✓ CTCAE v4,3& v5
- ✓Useful formulas – BSA, Cockroft-Gault, steroid dose convertor, etc.

Link to go to PSA Doubling time on webapp
https://webapp.oncoassist.com/public/index.php/login

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Regular PSA tests are required to monitor changes in PSA-DT and are helpful in identifying the risk of prostate cancer progression

- PSA-DT is a strong predictor of patient outcomes, including recurrence, mortality (all-cause and prostate cancer specific) with shorter doubling times corresponding to increased risk of recurrence[1,2,3]
- Both EAU and ESMO guidelines strongly recommend the use of PSA-DT to define risk of recurrence in patients post radical prostatectomy and post radiation therapy[3,4]
- In men on ADT alone, a PSA decline to < 4 ng/mL suggests a likely prolonged response and follow-up visits may be scheduled every 3 to 6 months provided the patient is asymptomatic or clinically improving [5]
- During follow-up of patients receiving ADT, check PSA and testosterone levels and monitor patients for symptoms associated with metabolic syndrome as a side effect of ADT[5]

1.Pound CR, Partin AW, Eisenberger MA et al. Natural History of Progression After PSA Elevation Following Radical Prostatectomy. JAMA. 1999;281 (17):1591–1597.

2. Roberts SG, Blute ML, Bergstralh EJ et al. PSA doubling time as a predictor of clinical progression after biochemical failure following radical prostatectomy for prostate cancer. Mayo Clin Proc. 2001 Jun;76(6):576–81.

3. Van den Broeck T, et al. Biochemical Recurrence in Prostate Cancer: The European Association of Urology Prostate Cancer Guidelines Panel Recommendations. Eur Ural Focus (2019).

4.Parker, C., Castro, E., Fizazi, K et al. on behalf of the ESMO Guidelines Committee (2020). Prostate cancer: ESMO Clinical Practice Guidelines for diagnosis, treatment and follow-up. Annals of Oncology, 31(9),1119–1134.

5. EAU – EANM – ESTRO – ESUR – SIOG Guidelines on Prostate Cancer. March 2020. Available at: https://uroweb.org/guideline/prostate-cancer/. (Accessed May 2021).

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EUROPEAN ASSOCIATION OF UROLOGY GUIDELINES[1]

6.5.17. ***Guideline for non-metastatic castrate-resistant disease***

Recommendation	Strength rating
Offer apalutamide, darolutamide or enzalutamide to patients with M0 CRPC and a high risk of developing metastasis (PSA-DT < 10 months) to prolong time to metastases and overall survival.	Strong

CRPC = castration-resistant prostate cancer; **PSA-DT** = prostate-specific antigen doubling time.

Reference: 1. EAU-EANM-ESTRO-ESUR-SIOG Guidelines on prostate Cancer. Accessed in June 2021 Available from: https://doi.org/10.1016/j.eururo.2020.09.042

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▼**NUBEQA® (darolutamid)** 300 mg filmdrasjerte tabletter. ATC-nr: L02B B06

Indikasjoner: Til behandling av voksne menn med ikke-metastatisk, kastrasjonsresistent prostatakreft (nmCRPC), som har høy risiko for å utvikle metastatisk sykdom**.**

Dosering: Anbefalt dose er 600 mg (2 tabletter à 300 mg) 2 ganger daglig, tilsv. total daglig dose 1200 mg. Medisinsk kastrasjon med GnRH-analog skal fortsette under behandling hos pasienter som ikke er kirurgisk kastrert.

Kontraindikasjoner: Overfølsomhet for virkestoffet eller noen av hjelpestoffene (laktose). Kvinner som er eller kan bli gravide

Forsiktighetsregler: Pasienter med alvorlig nedsatt nyrefunksjon eller moderat/alvorlig nedsatt leverfunksjon skal overvåkes nøye mht. bivirkninger pga. forhøyet eksponering. Hjerte/karl: Sikkerhet er ikke fastslått ved kardiovaskulær sykdom de siste 6 månedene. Ved forskrivning skal pasienter med klinisk signifikant kardiovaskulær sykdom behandles for disse tilstandene iht. fastsatte retningslinjer.

Ved risikofaktorer for QT-forlengelse i anamnesen og ved samtidig bruk av legemidler som kan forlenge QT-intervallet, skal nytte-/risikoforholdet vurderes, inkl. potensialet for torsades de pointes, før oppstart med darolutamid. Pasienter skal overvåkes med hensyn til bivirkninger av BCRP-, OATP1B1- og

OATP1B3-substrater, fordi samtidig administrering av darolutamid kan øke plasmakonsentrasjonen av disse substratene. Samtidig administrering av rosuvastatin bør unngås, med mindre det ikke finnes andre behandlingsalternativer

Bivirkninger: Svært vanlige (≥ 1/10) Fatigue/astenitilstander, redusert antall nøytrofile, økt bilirubin, økt ASAT. Vanlige (≥ 1/100, < 1/10) Iskemisk hjertesykdom og hjertesvikt, utslett, smerte i ekstremitet, muskler og skjelett, fraktur

Basert på SPC godkjent av SLV/EMA: 10/2020. Konsulter preparatomtalen (SPC) for mer informasjon **Pakninger og priser:** 112 stk. (blister) AUP 46.636,30NOK **Varenr:** 063426. **R.gr. C**, **H-resept**

For oppdaterte priser se; www.felleskatalogen.no

Kontaktinformasjon: Bayer AS, Drammensveien 288, NO-0283 OSLO, Postboks 193, 1325 Lysaker.

Tlf:+47 23 13 05 00, Faks: +47 23 13 05 01, www.bayer.no

▼ Dette legemiddelet er under spesiell overvåkning for å oppdage ny sikkerhetsinformasjon så raskt som mulig. Du kan bidra ved å melde enhver mistenkt bivirkning via relis.no

PP-NUB-NO-0063-1 Feb 2022

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