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*Frequency of imaging should be based on individual risk, age, PSADT, Gleason score and overall health. Bone scans should be performed as often as 6 to 12 months.
PSA: prostate-specific antigen; rPFS: radiographic progression-free survival; MFS: metastasis-free survival; HRQoL: health-related quality of life; AE: adverse events; NCCN: National Comprehensive Cancer Network; mHSPC: metastatic hormone-sensitive prostate cancer; PSADT: PSA doubling time.

29.7cm

21cm

21cm

20.9cm

PULL

Rapid, deep and durable PSA response improves lives.[3,6,13,14]
Prescribe **Erleada®** for your prostate cancer patients today.

ERLEADA® (Apalutamide) Film-Coated Tablets
Active Ingredient: Apalutamide. **Indication:** In adult men for the treatment of non-metastatic castration-resistant prostate cancer (nmCRPC) who are at high risk of developing metastatic disease; in adult men for the treatment of metastatic hormone-sensitive prostate cancer (mHSPC) in combination with androgen deprivation therapy (ADT). **Posology:** The recommended dose is 240 mg (four 60 mg tablets) as an oral single daily dose. It should be swallowed whole and can be taken with or without food. Medical castration with gonadotropin releasing hormone analogue (GnRHa) should be continued during treatment in patients not surgically castrated. If a ≥ Grade 3 toxicity or an intolerable adverse reaction is experienced by the patient, dosing should be held rather than permanently discontinuing treatment until symptoms improve to ≤ Grade 1 or original grade, then should be resumed at the same dose or a reduced dose (180 mg or 120 mg), if warranted. If the toxicity recurs at Grade 3 or higher, then the dose of apalutamide should be reduced to the next lower dose level (from 240 mg to 180 mg, and from 180 mg to 120 mg). A maximum of 2 dose level reductions (to 120 mg) is allowed. If further dose reductions are needed, apalutamide should be discontinued. Permanently discontinue ERLEADA® in patients who develop a seizure during treatment. **Contraindications:** Hypersensitivity to the active substance or to any of the excipients listed; women who are or may become pregnant. **Warnings and Precautions:** ERLEADA® is not recommended in patients with a history of seizures or other predisposing factors e.g. underlying brain injury, recent stroke (within one year), primary brain tumours or brain metastases. If a seizure develops during treatment with ERLEADA®, treatment should be discontinued permanently. Patients should be evaluated for fracture and fall risk before starting ERLEADA®, monitored and managed according to established treatment guidelines and use of bone-targeted agents should be considered. Monitor for signs and symptoms of ischemic heart disease and ischaemic cerebrovascular disorders, and management of risk factors should be optimised. Co-administration with warfarin and coumarin-like anticoagulants should be avoided. If co-administered, additional International Normalised Ratio (INR) monitoring should be conducted. Monitor for risk factors e.g. hypercholesterolaemia, hypertriglyceridaemia, or other cardio-metabolic disorders since the safety has not been established in patients with clinically significant recent cardiovascular disease. Consider discontinuation of ERLEADA® for Grade 3 and 4 events. In patients with a history of or risk factors for QT prolongation, physicians should assess the benefit-risk ratio including the potential for Torsade de pointes prior to initiating ERLEADA®. **Interactions:** No initial dose adjustment is necessary when ERLEADA® is co-administered with a strong inhibitor of CYP2C8 (e.g. gemfibrozil, clopidogrel) and CYP3A4 (e.g. ketoconazole, itraconazole, clarithromycin). However, a reduction of the ERLEADA® dose based on tolerability should be considered. CYP2C8 and CYP3A4 inducers are not expected to have clinically relevant effects. Concomitant use of ERLEADA® with medicinal products that are primarily metabolised by CYP3A4 (e.g. darunavir, felodipine, midazolam, simvastatin), CYP2C19 (e.g. diazepam, omeprazole), CYP2C9 (e.g. warfarin, phenytoin), substrates of P-gp (e.g. colchicine, dabigatran etexilate, digoxin), BCRP or OATP1B1 (e.g. lapatinib, methotrexate, rosuvastatin, repaglinide) can result in lower exposure of these medicinal products. Caution is advised when prescribing ERLEADA® with medicinal products known to prolong QT interval or able to induce Torsade de pointes e.g. class IA (quinidine, disopyramide) or class III (amiodarone, sotalol, dofetilide, ibutilide) antiarrhythmic medicinal products, methadone, moxifloxacin, antipsychotics (e.g. haloperidol). **Adverse Reactions:** Decreased appetite, hot flush, hypertension, diarrhoea, skin rash, fracture, arthralgia, fatigue, decreased weight and fall. **Pharmaceutical Form:** Film-coated tablet. **Pack Size:** Bottle of 120's.
Please refer to the full prescribing information before prescribing. Full prescribing information is available upon request. [EU SmPC vjun2021].

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20.6cm

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Glue

A randomised controlled trial analysis (AUA 2021)

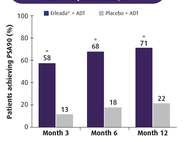
PSA kinetics in patients with advanced prostate cancer treated with apalutamide in TITAN study[1]

Erleada® (apalutamide) 60 mg tablets

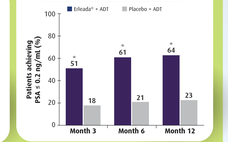
Erleada® demonstrates a **rapid, deep** and **durable PSA decline**[3]

- Nearly **3 times** more patients receiving **apalutamide + ADT** achieved deeper PSA decline (PSA90 & ≤ 0.2 ng/mL response) vs. ADT alone

PSA90 response rates, ITT



PSA ≤ 0.2 ng/mL response rates, ITT

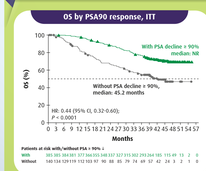


Adapted from Chi KN, et al. The Journal of Urology 2021.

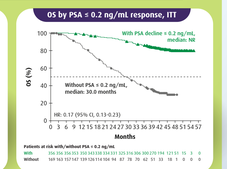
Adapted from Chi KN, et al. The Journal of Urology 2021.

A **deeper PSA decline** is associated with **significant improvement in OS** in mHSPC patients treated with Erleada®[3]

OS by PSA90 response, ITT



OS by PSA ≤ 0.2 ng/mL response, ITT

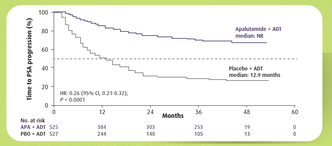


Adapted from Chi KN, et al. The Journal of Urology 2021.

Adapted from Chi KN, et al. The Journal of Urology 2021.

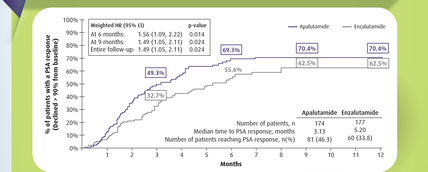
AUA: American Urological Association; PSA: prostate-specific antigen; ADT: androgen deprivation therapy; ITT: intention to treat; OS: overall survival; mHSPC: metastatic hormone-sensitive prostate cancer; NR: not reached; HR: hazard ratio; CI: confidence interval.

Erleada® significantly **improves time to PSA progression** in mHSPC patients (p < 0.0001)[6,13]



Adapted from Chi KN, et al. J Clin Oncol. 2021; Chowdhury S, et al. 2021.

ASCO-GU 2022 update: In a real-world study of individuals with **mHSPC, significantly more** individuals attained an **early and deep PSA90 response** with **Erleada®** vs. enzalutamide[7,14]



Adapted from Lowentritt B, et al. Journal of Clinical Oncology 2022.

- By 6 months and beyond, **significantly more** patients on **Erleada® attained PSA90 response** vs. enzalutamide (p = 0.024)[14]
- **PSA90 response** was attained **significantly earlier with Erleada®** vs. enzalutamide (p = 0.024; median time to PSA90: 3.1 vs. 5.2 months)[14]

***Disclaimer:** Enzalutamide is not approved for mHSPC indication in Malaysia.
mHSPC: metastatic hormone-sensitive prostate cancer; ADT: androgen deprivation therapy; PSA: prostate-specific antigen; OS: overall survival; APA: apalutamide; PBO: placebo; NR: not reached; HR: hazard ratio; CI: confidence interval; ASCO-GU: American Society of Clinical Oncology-Genitourinary.

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Creation date: April 2022
Creation number: CP-349618

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Erleada® (apalutamide) 60 mg tablets

PSA kinetics as promising **prognostic markers** of survival in advanced prostate cancer[1-3]

PSA kinetics, including PSA decline, early PSA response and undetectable PSA rate, are **early indications of therapeutic efficacy** in patients with **advanced prostate cancer**[1,2]

Among advanced prostate cancer patients, having **detectable PSA** at 12 months is associated with:[1]

3x
Increase in the hazard of metastasis (p = 0.013)

4.5x
Increase in the hazard of prostate cancer-specific death (p = 0.042)

2.5x
Increase in the hazard death from any cause (p = 0.042)

For healthcare professionals only.

Glue

20.9cm

21cm

21cm

PULL

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