

Workshops

Care for patients with advanced prostate cancer: Adding life to years **DDIs**

Professor Romano Danesi Dr Fabio Calabrò

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NL: Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via the national reporting system. Nederland:

Nederlands Bijwerkingen Centrum Lareb; Website: www.lareb.nl







XTANDI™ (enzalutamide) indications



XTANDI is indicated, as per the EMA SmPC:

- As monotherapy or in combination with ADT for the treatment of adult men with high-risk biochemical recurrent non-metastatic HSPC who are unsuitable for salvage radiotherapy
- In combination with ADT for the treatment of adult men with mHSPC
- For the treatment of adult men with high-risk non-metastatic CRPC
- For the treatment of adult men with mCRPC who are asymptomatic or mildly symptomatic after failure of ADT and in whom chemotherapy is not yet clinically indicated
- For the treatment of adult men with mCRPC whose disease has progressed on or after docetaxel therapy





DDIs: Introduction

Professor Romano Danesi

Department of Oncology and Hemato-Oncology University of Milano, Italy



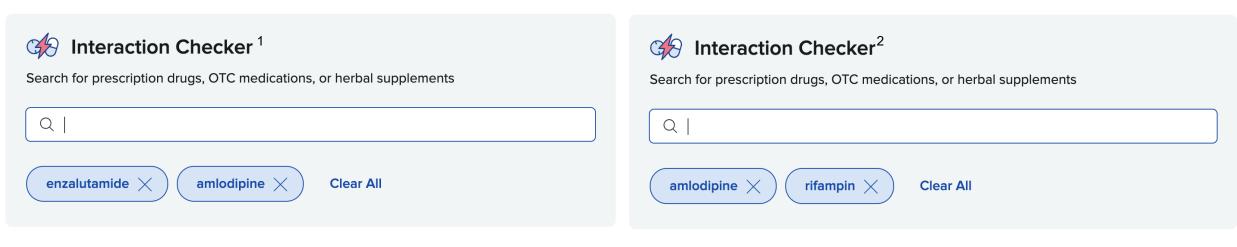
Disclosures

The speaker has received an honorarium from Astellas for this presentation

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Eisai			X		X	Χ	
AstraZeneca	X		X		X	Х	
BeiGene					X		
Janssen	Х		X		Х		
Novartis			X		X		
Lilly			X		X		
Incyte			X		X		
Johnson&Johnson			Х				
Sanofi			X		Х	Х	
Abbvie			X		Х		
Gilead					X	Х	

The effect of two CYP3A4 inducers on amlodipine is evaluated in two different ways (serious vs. significant): Why?





1 Interaction Found







Serious - Use Alternative

enzalutamide + amlodipine

enzalutamide will decrease the level or effect of amlodipine by affecting hepatic/intestinal enzyme CYP3A4 metabolism. Avoid or Use Alternate Drug.

rifampin + amlodipine

rifampin will decrease the level or effect of amlodipine by affecting hepatic/intestinal enzyme CYP3A4 metabolism. Use Caution/Monitor.

CYP, cytochrome P450; OTC, over-the-counter.

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^{1.} MedScape. Drug Interaction Checker: Enzalutamide + amlodipine. Available at: https://reference.medscape.com/drug-interactionchecker. Last accessed: July 2025; 2. MedScape. Drug Interaction Checker: Rifampin + amlodipine.. Available at: https://reference.medscape.com/drug-interactionchecker. Last accessed: July 2025; 2. MedScape. Drug Interaction Checker: Rifampin + amlodipine.. Available at: https://reference.medscape.com/drug-interactionchecker. Last accessed: July 2025.



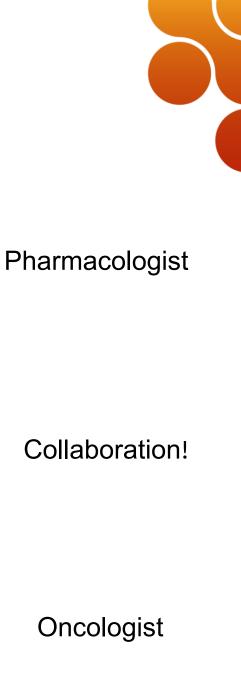


REVIEW

Clinical relevance and methodological approach for the assessment of drug—drug interactions in cancer patients: a position statement from the Italian Association of Medical Oncology (AIOM) and the Italian Society of Pharmacology (SIF)

M. Del Re¹, R. Roncato², A. Argentiero³, L. Berrino⁴, A. Botticelli⁵, A. Capuano⁴, S. Di Donato⁶, S. Fogli⁷, D. Marino⁸, G. Rodriguenz⁹, D. Speranza¹⁰, F. Perrone¹¹, N. Silvestris^{3*†‡} & R. Danesi^{12*†‡}

The assessment of a DDI requires a multidisciplinary approach



Perpetrator drug(s) Metabolic/PD interaction Victim drug(s) Therapeutic index (How tolerable is/are PK/PD covariate the victim drug(s)?) (patient specific) Clinical risk and severity of DDI Mitigation strategies

Benefit-to-risk ratio
(Is changing a pre-existing therapy on which the patient is stabilised an acceptable risk?)

Figure adapted from Del Re M, et al. *ESMO Open* 2025. DDI, drug-drug interaction; PD, pharmacodynamics; PK, pharmacokinetics. Del Re M, et al. *ESMO Open* 2025;10:105119. MAT-NL-XTD-2025-00039 | July 2025

- Key messages
- Polypharmacy is common in the population of patients treated for mHSPC¹
- Although DDI checkers often flag potential interactions between ARPIs and commonly prescribed drugs such as calcium channel blockers and antidepressants, these drugs have a wide therapeutic index and can generally be used alongside ARPIs without clinically relevant interactions^{1,2}
- Be aware that checkers overestimate the risk of interactions and do not discriminate between clinically significant and non-clinically significant DDIs. Consistency is also an issue²
- My recommendation is to choose the most appropriate oncological drug for the patient²
- If necessary, review the non-oncological therapy that the patient is taking²
- In certain cases, dose alterations or additional monitoring may be required to reduce the risk of adverse outcomes^{1,2}





DDIs: Case study

Dr Fabio Calabrò

Regina Elena National Cancer Institute, Rome, Italy

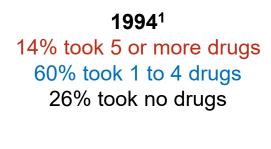


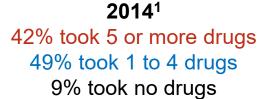
Disclosures

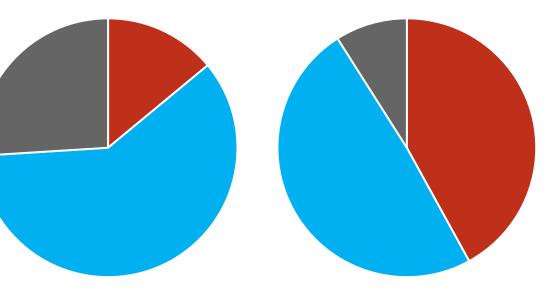
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Relationship	Company/Organization
Advisory boards	Pfizer, BMS, Ipsen, MSD, Astra Zeneca, Merck, Accord, Gilead, Novartis, AAA Pharma, J&J, Astellas
Consulting	J&J, Astellas
Honoraria	Astellas
Financial	None
Research support	None
Stock ownership	None

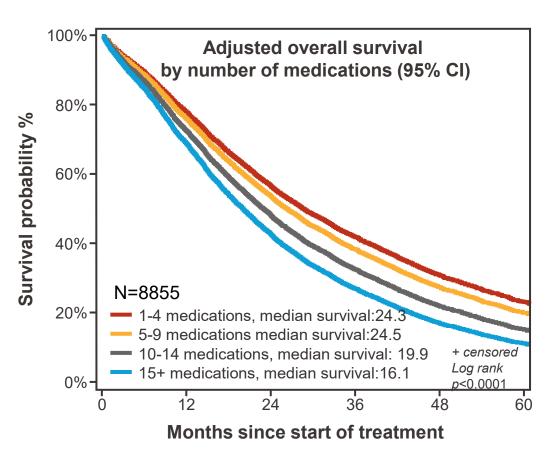
Polypharmacy is a growing problem







Adjusted overall survival by number of medications in patients with mCRPC²



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Figures adapted from Lown Institute. Medication Overload: America's Other Drug Problem¹ and Pickett CR et al, *Prostate Cancer* 2024;2024:6863066.² CI, confidence interval; mCRPC, metastatic castration-resistant prostate cancer

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^{1.} Lown Institute. Medication Overload: America's Other Drug Problem (April 2019). Available at: https://lowninstitute.org/wp-content/uploads/2019/09/xs-medication-overload-lown-web.pdf. Last accessed: July 2025; 2. Pickett CR et al, *Prostate Cancer* 2024;2024:6863066.

Case study

- 75 y.o. gentleman
- ECOG PS=1
- No relevant family history
- Hypertension
- Atrial fibrillation
- Dyslipidemia
- Mild depression
- Type 2 diabetes



Screening PSA= 35 ng/ml MRI PI-RADS 5 Biopsy adenocarcinoma GG 5



PSMA PET
PSMA uptake in prostate gland
Multiple vertebrae and lymph nodes

12



Losartan, amlodipine bisoprolol, apixaban, simvastatin, citalopram, metformin

ECOG, Eastern Cooperative Oncology Group; GG, grade group; MRI, magnetic resonance imaging; PET, positron emission tomography; PI-RADS, Prostate Imaging Reporting and Data System; PS, performance score; PSA, prostate-specific antigen; PSMA, prostate-specific membrane antigen; y.o., years old.

Case provided by the speaker.

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Systemic treatment



What systemic treatment would you recommend for this patient?

ADT alone

ADT + Docetaxel

ADT + ARPI

Only symptomatic RT

ADT + ARPI + Docetaxel

Case study

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Screening PSA = 35 ng/ml MRI PI-RADS 5 Biopsy adenocarcinoma GG 5



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Losartan, amlodipine, bisoprolol, apixaban, simvastatin, citalopram, metformin

Triptorelin + enzalutamide

Drug—drug interactions with enzalutamide

- ✓ Enzalutamide is a moderate inducer of CYP2C9 and CYP2C19 and a strong inducer of CYP3A4
- ✓ Avoid strong CYP2C8 inhibitors as they can increase the AUC of enzalutamide by 326%
 - ✓ If coadministration cannot be avoided, reduce the dosage of enzalutamide.
- ✓ No dose adjustments are necessary when enzalutamide is administered with inducers of CYP3A4 or CYP2C8
- ✓ Interactions with certain medicinal products that are eliminated through metabolism or active transport are expected. If their therapeutic effect is of large importance to the patient, and dose adjustments are not performed based on monitoring of efficacy or plasma concentrations, these medicinal products are to be avoided or used with caution

Systemic treatment

Without knowing of any potential DDIs, what would you recommend?

Reduce the dose of enzalutamide

Use online DDI checker

Increase the dose of enzalutamide

Adjust concomitant medications

Do not change the dose of enzalutamide

Basic recommendations (in theory)



therapeutic index

Two strategies to avoid negative interactions with enzalutamide

Choose a drug not metabolised by CYP3A4

Choose a drug with a wide

Basic recommendations (in practice)





Enter a drug, OTC or herbal supplement:	

XTANDI (enzalutamide) tablets. Available at https://www.ema.europa.eu/en/documents/product-information/xtandi-epar-product-information-en.pdf



DRUG INTERACTIONS FOOD INTERACTIONS

ADD DRUG TO CHECK FOR INTERACTIONS

Tylenol

Please enter 3 or more characters

Ask your pharmacist or pharmacologist!
Involve them in the MDT²

DDI checkers shown are examples only, and not exhaustive.

CYP, cytochrome P450; MDT, multidisciplinary team; OTC, over-thr-counter.

1. Drug Interaction Checker. Drugs.com. Available at: <u>Drug Interaction Checker - Find Unsafe Combinations</u>. 2. Speaker's opinion.

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ARPI potential interactions: Antihypertensives

	Abirate	rone acetate	Enzalut	tamide	Apalut	amide	Darolutamide	
	Risk Level	Mechanism-Result	Risk Level	Mechanism-Result	Risk Level	Mechanism-Result	Risk Level	Mechanism- Result
Antihypertensives								
Ramipril	Α	_	Α	_	Α	_	Α	_
Perindopril	Α	_	Α	_	Α	_	Α	_
Lisinopril	Α	_	Α	_	Α	_	Α	_
Enalapril	Α	_	Α	_	Α	_	Α	_
Trandolapril	Α	_	Α	_	Α	_	Α	_
Fosinopril	Α	_	Α	_	Α	_	Α	_
Candesartan	Α	_	Α	_	Α	_	Α	_
Valsartan	Α	-	Α	-	Α	-	С	OATP1B1-1B3 Valsartan†
Irbesartan	Α	_	Α	_	Α	_	Α	_
Telmisartan	Α	_	Α	_	Α	_	Α	_
Losartan	Α	_	В	CYP3A4 CYP2C9 Losartan↓	В	CYP3A4 CYP2C9 Losartan↓	Α	_
Amlodipine	Α	_	С	CYP3A4 Amlodipine↓	С	CYP3A4 Amlodipine↓	Α	-
Lercanidipine	Α	-	С	CYP3A4 Lercanidipine↓	С	CYP3A4 Amlodipine↓	Α	-
Nifedipine	Α	-	D	CYP3A4 Nifedipine↓	D	CYP3A4 Nifedipine↓	Α	-
Verapamil	Α	-	D	CYP3A4 Verapamil↓	D	CYP3A4 Verapamil↓	В	CYP3A4/P-gp Darolutamide
Diltiazem	Α	-	D	CYP3A4 Diltiazem↓	D	CYP3A4 Diltiazem↓	Α	_
Indapamide	Α	_	Α	_	Α	_	Α	_
HCTZ	Α	_	Α	_	Α	_	Α	_
Metoprolol	С	CYP2D6 Metoprolol↑	Α	-	Α	_	Α	_
Bisoprolol	Α	-	С	CYP3A4 Biso prolo I↓	С	CYP3A4 Bisoprolol↓	Α	_
Carvedilol	С	CYP2D6 Bisoprolol↑	Α	_	Α	-	Α	-
Nebivolol	С	CYP2D6	Α	_	Α	_	Α	_



B No action needed

C Monitor therapy

D Consider therapy modification

X Avoid combination

Adapted from Bolek H, et al, 2024. Table created based on UpToDate® Lexicomp® Drug Interactions.

ARPI, androgen receptor pathway inhibitor; CYP, cytochrome P450; HCTZ, hydrochlorothiazide; OATP, organic anion transporting polypeptide; P-gp, P-glycoprotein. Bolek H, et al. *ESMO Open* 2024;9:103736.

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ARPI potential interactions: Oral anticoagulants and lipid-lowering drugs

	Abiraterone acetate		Enzalut	Enzalutamide A		Apalutamide		tamide
	Risk Level	Mechanism-Result	Risk Level	Mechanism-Result	Risk Level	Mechanism-Result	Risk Level	Mechanism- Result
Oral anticoagulants								
Rivaroxaban	Α	_	D	CYP3A4 Rivaroxaban ↓	X	CYP3A4/P-gp Rivaroxaban ↓	Α	_
Apixaban	Α	_	D	CYP3A4 Apixaban ↓	X	CYP3A4/P-gp Apixaban ↓	Α	-
Edoxaban	A	-	С	P-gp Edoxaban↑	D	P-gp Edoxaban ↓	Α	-
Dabigatran	Α	-	С	P-gp Dabigatran↑	Х	P-gp Dabigatran ↓	Α	-
Warfarin	A	-	D	CYP2C9/CYP3A4 Warfarin ↓	С	CYP2C9 Warfarin ↓	Α	_

A No known interaction

B No action needed

C Monitor therapy

	Abirate	Abiraterone acetate		tamide	Apalut	Apalutamide		Darolutamide	
	Risk Level	Mechanism-Result	Risk Level	Mechanism-Result	Risk Level	Mechanism-Result	Risk Level	Mechanism- Result	
Lipid-lowering drugs									
Rosuvastatin	С	OATP1B1 Myopathic effect	Α	_	С	BCRP/OATP1B1 Ros uvastatin↓	D	BCRP/ OATP1B1-1B3 Rosuvastatin†	
Atorvastatin	С	OATP1B1 Myopathic effect	С	CYP3A4 Atorvastatin↓	С	CYP3A4 Atorvastatin↓	С	OATP1B1-1B3 Atorvastatin	
Simvastatin	С	OATP1B1 Myopathic effect	С	CYP3A4 Simvastatin↓	С	CYP3A4 Simvastatin↓	С	OATP1B1-1B3 Simvastatin†	
Pravastatin	С	OATP1B1 Myopathic effect	Α	_	Α	_	С	OATP1B1-1B3 Pravastatin†	
Ezetimibe	Α		Α	-	Α	-	С	OATP1B1-1B3 Ezetimibe†	
Fenofibrate	Α	_	Α	_	Α	_	Α	_	

D Consider therapy modification

X Avoid combination

Tables adapted from Bolek H, et al, 2024.

ARPI, androgen receptor pathway inhibitor; BCRP, breast cancer resistance protein; CYP, cytochrome P450; OATP, organic anion transporting polypeptide; P-gp, P-glycoprotein. Bolek H, et al. *ESMO Open* 2024;9:103736.

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ARPI potential interactions: Antidepressants

	Abirate	rone acetate	Enzalut	amide	Apalut	amide	Darolutamide	
	Risk Level	Mechanism-Result	Risk Level	Mechanism-Result	Risk Level	Mechanism-Result	Risk Level	Mechanism- Result
Antidepressants								
Trazodone	В	CYP2D6 Trazodone↑	D	CYP3A4 Trazodone ↓	D	CYP3A4 Trazodone ↓	A	_
(Es)citalopram	Α	_	С	CYP3A4/CYP2C19 Escitalopram↓	С	CYP3A4/CYP2C19 Escitalopram↓	Α	_
Venlafaxine	В	CYP2D6 conversion to active metabolite ODV↓	Α	-	A	-	A	_
Duloxetine	В	CYP2D6 Duloxetine↑	Α	-	Α	_	Α	_
Mirtazapine	Α	_	С	CYP3A4/ Mirtazapine↓	С	CYP3A4/ Mirtazapine↓	A	_
Sertraline	Α	_	С	CYP3A4/CYP2C9 CYP2C19 Sertraline	С	CYP3A4/CYP2C9 CYP2C19 Sertraline	Α	_
Fluoxetine	Α	_	Α	_	Α	_	Α	_
Amitriptyline	С	CYP2D6 Amitriptyline↑	Α	-	Α	-	Α	_
Nortriptyline	С	CYP2D6 Nortriptyline↑	Α	_	A	_	A	_
Bupropion	Α	_	Α	_	Α	_	Α	_
Paroxetine	С	CYP2D6 Paroxetine↑	Α	_	Α	_	A	_
Sedatives								
Lorazepam	Α	_	Α	_	Α	_	Α	_
Zopiclone	Α	_	С	CYP3A4 Zopiclone ↓	С	CYP3A4 Zopiclone ↓	Α	_
Clonazepam	Α	_	С	CYP3A4 Clonazepam ↓	С	CYP3A4 Clonazepam ↓	A	_
Oxazepam	Α	_	Α	_	Α	_	Α	_
Temazepam	Α	_	Α	_	Α	_	Α	_
Alprazolam	Α	-	С	CYP3A4 Alprazolam ↓	С	CYP3A4 Alprazolam ↓	Α	_
Diazepam	Α	-	С	CYP3A4/CYP2C19 Diazepam ↓	С	CYP3A4/CYP2C19 Diazepam ↓	Α	-

A No known interaction

B No action needed

C Monitor therapy

D Consider therapy modification

X Avoid combination

Adapted from Bolek H, et al, 2024. CYP, cytochrome P450; DDI, drug-drug interaction. Bolek H et al. *ESMO Open* 2024;9:103736. MAT-NL-XTD-2025-00039 | July 2025

ARPI potential interactions: Oral antidiabetics



	Abirate	rone acetate	Enzalut	tamide	Apaluta	Apalutamide		Darolutamide	
	Risk Level	Mechanism-Result	Risk Level	Mechanism-Result	Risk Level	Mechanism-Result	Risk Level	Mechanism- Result	
Oral Antidiabetics									
Metformin	Α	_	Α	_	Α	_	Α	_	
Gliclazide	Α	_	С	CYP2C9/CYP3A4 Gliclazide ↓	Α	_	Α	_	
Glyburide	A	_	С	CYP2C9/CYP3A4 Glyburide ↓	Α	_	С	OATP1B1-1B3 Glyburide↑	
Pioglitazone	С	? Hypoglycemia	Α	_	Α	_	Α	_	
Sitagliptin	Α	_	Α	_	Α	_	Α	_	
Linagliptin	Α	_	D	CYP3A4 Linagliptin ↓	D	CYP3A4/P-gp Linagliptin ↓	Α	_	
Saxagliptin	A	_	С	CYP3A4 Saxagliptin ↓	С	CYP3A4/P-gp Saxagliptin ↓	Α	_	
Empagliflozin	Α	_	Α	_	Α	_	Α	_	
Dapagliflozin	Α	_	Α	_	Α	_	Α	_	
Canagliflozin	Α	_	Α	_	Α	_	Α	_	

- A No known interaction
- B No action needed
- C Monitor therapy
- D Consider therapy modification
- X Avoid combination

Case study

- 75 y.o. gentleman
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Screening PSA = 35 ng/ml MRI PI-RADS 5 Biopsy adenocarcinoma GG 5



PSMA PET
PSMA uptake in prostate gland
Multiple vertebrae and lymph nodes



Losartan, amlodipine, bisoprolol, apixaban, simvastatin, citalopram, metformin

Triptorelin + enzalutamide

Case study: Potential interactions with enzalutamide and adjustments made to concomitant treatments¹

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Original treatment ¹	DDI identified/predicted with enzalutamide ²	Replacement treatment ¹	Management ¹
Losartan ²	Interaction with CYP3A4, CYP2C9; leading to decreased losartan level	Valsartan	
Amlodipine ²	Interaction with CYP3A4; leading to decreased amlodipine level	-	Monitor therapy: Amlodipine dose increase is required
Bisoprolol ²	Interaction with CYP3A4; leading to decreased bisoprolol level	Nebivolol	
Apixaban ²	Interaction with CYP3A4; leading to decreased apixaban level	Dabigatran	Monitor therapy: Dabigatran levels may be increased due to inhibition of P-gp by enzalutamide
Simvastatin ²	Interaction with CYP3A4; leading to decreased simvastatin level	Rosuvastatin	
(Es)citalopram ²	Interaction with CYP3A4, CYP2C19; leading to decreased Escitalopram level	-	Monitor therapy
Metformin ²	No known interaction	-	

CYP, cytochrome P450; DDI, drug-drug interaction; P-gp, P-glycoprotein.

1. Speaker's own opinion; 2. Bolek H et al. *ESMO Open* 2024;9:103736.

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Case study

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Screening PSA = 35 ng/ml MRI PI-RADS 5 Biopsy adenocarcinoma GG 5



PSA dropped to 0.1 ng/ml Patient complains hot flushes Depressive mood



Systemic treatment



For this patient do you recommend to

Consider intermittent treatment

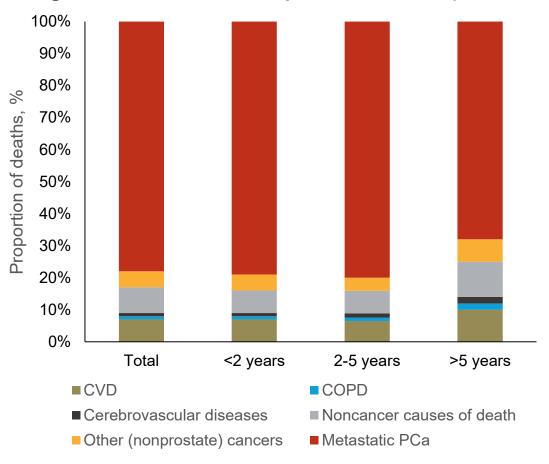
Stop treatment

Psychiatric consultation

Listen to patient preferences

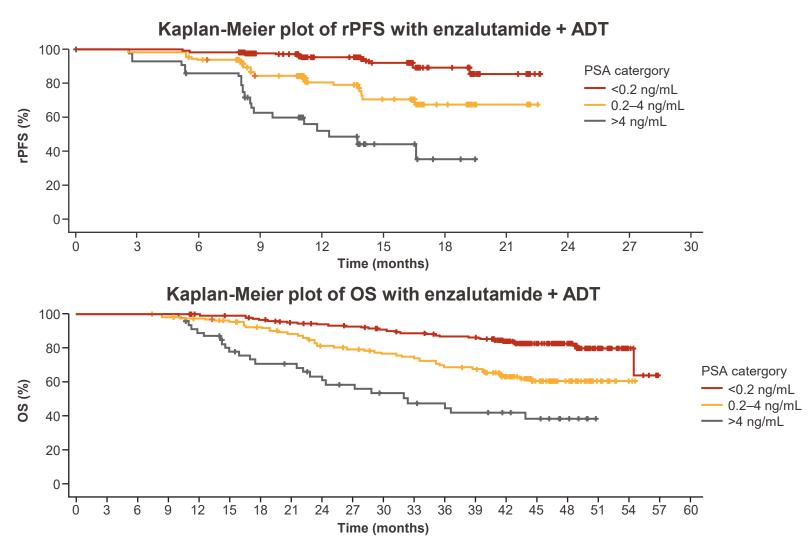
Causes of death not related to prostate cancer

Causes of death during each latency period after diagnosis with metastatic prostate cancer (N=26,168)



35% of deaths NOT due to prostate cancer after 5 years in the US from 2000 to 2016

The prognostic value of PSA decline in the ARCHES trial



Figures adapted from Azad AA, et al. *JAMA Network Open* 2025.

ADT, androgen deprivation therapy; OS, overall survival; PSA, prostate-specific antigen; rPFS, radiographic progression-free survival. Azad AA, et al. *JAMA Network Open*. 2025;8:e258751.

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A-DREAM: ADT interruption in patients responding to ARPIs^{1,2}





Reinitiation triggers:

- PSA ≥5 ng/mL
- Radiographic change (PCWG3)
- Prostate cancer-related symptoms

Interrupt ADT + ARPI

Assessments:

- PSA/testosterone every 3 months
 - Scans at least every 6 months
 - QoL every 6 months

After Month 18:

Continue treatment (physician discretion)



Treatment free* at 18 months

Selected secondary endpoints: Time to eugonadal testosterone, duration off therapy, QoL

Exploratory endpoints: rPFS, TTNT, OS (CSS/NCSS), cost

Eligibility:

- mHSPC on ADT + ARPI
- PSA < 0.2 ng/ml after 18–24 months ADT (must have received ARPI for at least 360 days)

*The proportion of men who experience 18-month treatment-free interval from therapy with eugonadal testosterone (to ≥150 ng/ml) after treatment interruption.

ADT, androgen deprivation therapy; ARPI, androgen receptor pathway inhibitor; CSS, cancer-specific survival; mHSPC, metastatic hormone-sensitive prostate cancer; NCSS, noncancer-specific survival; OS, overall survival; PSA, prostate-specific antigen; QoL, quality of life; rPFS, radiographic progression-free survival; TTNT, time to next treatment.

1. NCT05241860. Available at: https://clinicaltrials.gov/study/NCT05241860. Last accessed: July 2025; 2. Sayyid R. UroToday.com Available at: https://www.urotoday.com/conference-highlights/asco-2024/asco-2024/asco-2024-prostatecancer/152503-asco-2024-a-phase-2-trial-of-adt-interruption-in-patients-responding-exceptionally-to-ar-pathway-inhibitor-in-metastatic-hormone-sensitive-prostate-cancer-a-dream-alliance-a032101.html. Last accessed July 2025. MAT-NL-XTD-2025-00039 | July 2025

DDIs in prostate cancer: Conclusions

- Prostate cancer patients have high risk of potential DDIs due to frequently-associated comorbidities and polypharmacy in this population
- DDIs can result in adverse PK or PD effects that can impact on efficacy and adverse events from the medications being taken
- Any potential interactions must be evaluated before starting treatment with ARPIs
- Most of the potential DDIs can be managed
- Oncology pharmacists should be included in the healthcare teams
- Paying close attention to DDIs is essential to improve the outcome of prostate cancer patients treated with ARPIs, helping to improve the potential efficacy and tolerability of medicines

ARPI, androgen receptor pathway inhibitor; DDI, drug-drug interaction; PD, pharmacodynamic; PK, pharmacokinetic. Speaker's own opinion.

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Please refer to the EMA SmPC for XTANDI™ (enzalutamide) via the following link: https://www.ema.europa.eu/en/documents/product-information/xtandi-epar-product-information en.pdf



Scan/click here for the XTANDI™ UK prescribing information



Scan/click here for the XTANDI™ NL SmPC