Xtandi®
(enzalutamide)
40 mg tablets | 80 mg tablets

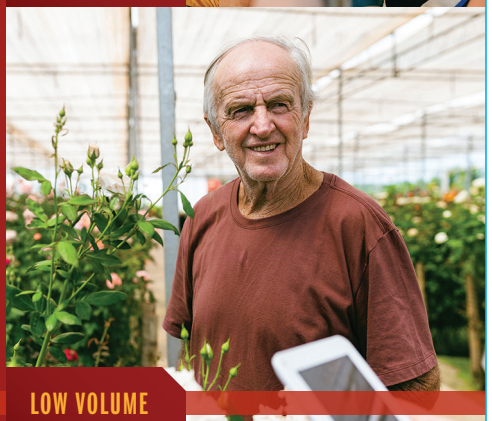
PATIENT PROFILES

XTANDI in mCSPC

HIGH VOLUME

LOW VOLUME

HIGH VOLUME



LOW VOLUME

Indications

XTANDI is indicated for the treatment of patients with:

- nonmetastatic castration-sensitive prostate cancer (nmCSPC) with biochemical recurrence at high risk for metastasis (high-risk BCR)
- metastatic castration-sensitive prostate cancer (mCSPC)
- castration-resistant prostate cancer (CRPC)

Select Safety Information

Seizure occurred in 0.6% of patients receiving XTANDI in eight randomized clinical trials. In a study of patients with predisposing factors for seizure, 2.2% of XTANDI-treated patients experienced a seizure. It is unknown whether anti-epileptic medications will prevent seizures with XTANDI. Patients in the study had one or more of the following predisposing factors: use of medications that may lower the seizure threshold, history of traumatic brain or head injury, history of cerebrovascular accident or transient ischemic attack, and Alzheimer's disease, meningioma, or leptomeningeal disease from prostate cancer, unexplained loss of consciousness within the last 12 months, history of seizure, presence of a space occupying lesion of the brain, history of arteriovenous malformation, or history of brain infection. Advise patients of the risk of developing a seizure while taking XTANDI and of engaging in any activity where sudden loss of consciousness could cause serious harm to themselves or others. Permanently discontinue XTANDI in patients who develop a seizure during treatment.

Please see Important Safety Information on pages 14-15 and accompanying Full Prescribing Information in pocket.

Not actual patients or patient cases; content for illustrative purposes only.

TABLE OF CONTENTS

Not actual patients or patient cases; content for illustrative purposes only.

Select Safety Information

Posterior Reversible Encephalopathy Syndrome (PRES) There have been reports of PRES in patients receiving XTANDI. PRES is a neurological disorder that can present with rapidly evolving symptoms including seizure, headache, lethargy, confusion, blindness, and other visual and neurological disturbances, with or without associated hypertension. A diagnosis of PRES requires confirmation by brain imaging, preferably MRI. Discontinue XTANDI in patients who develop PRES.

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ARCHES STUDY DESIGN

The ARCHES trial assessed the efficacy and safety of **XTANDI** + GnRH therapy* vs placebo + GnRH therapy* in patients with **mCSPC**[1]

mCSPC

Patient enrollment[1]	1150
Eligibility criteria included[2]	• mCSPC • ECOG Performance Status of 0 or 1
Treatment[1]	XTANDI 160 mg/day + GnRH therapy* (n = 574)
Comparator[1]	Placebo + GnRH therapy* (n = 576)
Randomization[1]	1:1
Chemotherapy[1]	• Prior docetaxel use allowed • Docetaxel-naive allowed
Stratification factors[1]	• Volume of disease 63% had high-volume† disease | 37% had low-volume disease • Prior docetaxel therapy for prostate cancer (none, 1 to 5, or 6 cycles) 82% had no prior docetaxel treatment | 18% had prior docetaxel treatment
Baseline patient characteristics included[1]	• 66% of patients had a Gleason score of ≥ 8 • 12% of patients received concomitant bone-targeted agents (bisphosphonates or RANKL inhibitors), which included both prostate and non-prostate cancer indications • ECOG Performance Status of 0 (78%) or 1 (22%)
Treatment duration[1]	Treatment continued until radiographic disease progression‡, start of new treatment, unacceptable toxicity, or withdrawal
Exclusion criteria included[3]	Predisposing factors for seizure and clinically significant cardiovascular disease
Select endpoints[1,2]	• Primary: radiographic progression-free survival§ • Secondary: overall survival; time to start of new antineoplastic therapy; time to PSA progression; PSA undetectable rate; time to deterioration of urinary symptoms; health-related quality of life

ECOG, Eastern Cooperative Oncology Group; **GnRH**, gonadotropin-releasing hormone; **PSA**, prostate-specific antigen; **RANKL**, receptor activator of nuclear factor kappa B ligand.

***Or after bilateral orchiectomy.**[1]

†Defined as metastases involving the viscera or, in the absence of visceral lesions, ≥ 4 bone lesions, ≥ 1 of which must be in a bony structure beyond the vertebral column and pelvic bone.[1]

‡Radiographic disease progression was defined by identification of ≥ 2 new bone lesions on a bone scan with confirmation (Prostate Cancer Working Group 2 [PCWG2] criteria) and/or progression in soft-tissue disease.[1]

§Radiographic progression-free survival was defined as the time from randomization to radiographic disease progression at any time or death within 24 weeks after study drug discontinuation.[1]

DE NOVO mCSPC, HIGH VOLUME

NAME Rafael AGE 62

OCCUPATION Restaurant owner

LIFESTYLE I love hiking and bike riding

MARITAL STATUS Divorced

SUPPORT My ex-wife is my caregiver

Not an actual patient or patient case; content for illustrative purposes only.

BELIEFS *"I can't believe I have mCSPC. I've never heard of the disease, and I don't know anyone with the diagnosis. I want to learn more about mCSPC and treatment options."*

ATTITUDES *"I've read about cancer treatments from online forums. I know there are many options and it's important to learn about the side effects. I'm interested in learning from experts in the community."*

GOAL *"My goal is to seek treatment that may help delay progression."*

Not an actual patient testimonial; testimonial based on research of patients with similar disease states and stages discussed on page.

CLINICAL PROFILE

PROSTATE CANCER CLINICAL HISTORY

2 MONTHS AGO

- Visited urologist due to severe pain when urinating
- **Comorbidity:** type 2 diabetes
- No prior history of prostate cancer
- **PSA:** 17 ng/mL

CURRENT CLINICAL EVALUATION

- Diagnosis of de novo mCSPC with high-volume disease
- **ECOG Performance Status:** 0
- **Gleason score:** 8 (4 + 4)
- **Prostate-specific membrane antigen (PSMA) positron emission tomography (PET) results:** additional lesions including 2 metastases in sacral spine, 2 metastases in thoracic vertebral bones, and 2 metastases in the liver
- GnRH therapy initiated

Select Safety Information

Hypersensitivity reactions, including edema of the face (0.5%), tongue (0.1%), or lip (0.1%) have been observed with XTANDI in eight randomized clinical trials. Pharyngeal edema has been reported in post-marketing cases. Advise patients who experience any symptoms of hypersensitivity to temporarily discontinue XTANDI and promptly seek medical care. Permanently discontinue XTANDI for serious hypersensitivity reactions.

Ischemic Heart Disease In the combined data of five randomized, placebo-controlled clinical studies, ischemic heart disease occurred more commonly in patients on the XTANDI arm compared to patients on the placebo arm (3.5% vs 2%). Grade 3-4 ischemic events occurred in 1.8% of patients on XTANDI versus 1.1% on placebo. Ischemic events led to death in 0.4% of patients on XTANDI compared to 0.1% on placebo. Monitor for signs and symptoms of ischemic heart disease. Optimize management of cardiovascular risk factors, such as hypertension, diabetes, or dyslipidemia. Discontinue XTANDI for Grade 3-4 ischemic heart disease.

Please see Important Safety Information on pages 14-15 and accompanying Full Prescribing Information in pocket.

DE NOVO mCSPC, LOW VOLUME

NAME Andre AGE 58

OCCUPATION Businessman

LIFESTYLE Busy with frequent travel

MARITAL STATUS Married

SUPPORT My wife is my caregiver

Not an actual patient or patient case; content for illustrative purposes only.

BELIEFS *"I'm still in shock and quite overwhelmed by my diagnosis. mCSPC and the treatment for it are unfamiliar to me. I want to learn more about mCSPC and treatment options."*

ATTITUDES *"Sharing my questions with my doctor has helped me learn about treatment and lifestyle choices. Searching online for resources has been too much to digest."*

GOAL *"My goal is to seek guidance from my doctor for an effective treatment option."*

Not an actual patient testimonial; testimonial based on research of patients with similar disease states and stages discussed on page.

CLINICAL PROFILE

PROSTATE CANCER CLINICAL HISTORY

3 MONTHS AGO

- Visited emergency room due to severe back pain
- **Comorbidity:** hypertension
- No prior history of prostate cancer
- **PSA:** 6 ng/mL

CURRENT CLINICAL EVALUATION

- Diagnosis of de novo mCSPC with low-volume disease
- **ECOG Performance Status:** 0
- **Gleason score:** 8 (4 + 4)
- **Conventional imaging results:** positive pelvic lymph nodes, 1 metastasis in sacral spine, and 2 metastases in pelvic bones
- GnRH therapy initiated

Select Safety Information

Falls and Fractures occurred in patients receiving XTANDI. Evaluate patients for fracture and fall risk. Monitor and manage patients at risk for fractures according to established treatment guidelines and consider use of bone-targeted agents. In the combined data of five randomized, placebo-controlled clinical studies, falls occurred in 12% of patients treated with XTANDI compared to 6% of patients treated with placebo. Fractures occurred in 13% of patients treated with XTANDI and in 6% of patients treated with placebo.

Embryo-Fetal Toxicity The safety and efficacy of XTANDI have not been established in females. XTANDI can cause fetal harm and loss of pregnancy when administered to a pregnant female. Advise males with female partners of reproductive potential to use effective contraception during treatment with XTANDI and for 3 months after the last dose of XTANDI.

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RECURRENT mCSPC, HIGH VOLUME

NAME Ken AGE 72

OCCUPATION Retired IT Professional

LIFESTYLE I enjoy fishing and spending time with my grandchildren

MARITAL STATUS Married

SUPPORT My Son-in-law is my caregiver

MEET KEN

Not an actual patient or patient case; content for illustrative purposes only.

BELIEFS *"While I hoped that the past treatment had worked for me, I am aware that everyone responds differently to different treatments. I understand it's important to work with my healthcare team to learn about treatment options that are compatible with my lifestyle."*

ATTITUDES *"I've slowed down my routine after my diagnosis. Now, I make use of my time by seeking out support groups for men with my condition."*

GOAL *"My goal is to live in the moment."*

Not an actual patient testimonial; testimonial based on research of patients with similar disease states and stages discussed on page.

CLINICAL PROFILE

PROSTATE CANCER CLINICAL HISTORY

3 YEARS AGO

- Diagnosis of locally advanced/regional prostate cancer
- **Comorbidity:** mild chronic obstructive pulmonary disease
- **PSA:** 7 ng/mL at initial diagnosis
- **Gleason score:** 9 (5 + 4)
- Treated with radical prostatectomy

CURRENT CLINICAL EVALUATION

- Diagnosis of recurrent mCSPC with high-volume disease
- **ECOG Performance Status:** 1
- **PSA:** 5.4 ng/mL
- **PET/magnetic resonance imaging (MRI) results:** 2 metastases in the pelvic bones, 2 metastases in the thoracic spine, and 2 metastases in the liver
- GnRH therapy initiated

Select Safety Information

Adverse Reactions (ARs) In the data from the five randomized placebo-controlled trials, the most common ARs (≥ 10%) that occurred more frequently (≥ 2% over placebo) in XTANDI-treated patients were musculoskeletal pain, fatigue, hot flush, constipation, decreased appetite, diarrhea, hypertension, hemorrhage, fall, fracture, and headache. In the bicalutamide-controlled study, the most common ARs (≥ 10%) reported in XTANDI-treated patients were asthenia/fatigue, back pain, musculoskeletal pain, hot flush, hypertension, nausea, constipation, diarrhea, upper respiratory tract infection, and weight loss.

In AFFIRM, the placebo-controlled study of metastatic CRPC (mCRPC) patients who previously received docetaxel, Grade 3 and higher ARs were reported among 47% of XTANDI-treated patients. Discontinuations due to ARs were reported for 16% of XTANDI-treated patients. In PREVAIL, the placebo-controlled study of chemotherapy-naive mCRPC patients, Grade 3-4 ARs were reported in 44% of XTANDI patients and 37% of placebo patients. Discontinuations due to ARs were reported for 6% of XTANDI-treated patients. In TERRAIN, the bicalutamide-controlled study of chemotherapy-naive mCRPC patients, Grade 3-4 ARs were reported in 39% of XTANDI patients and 38% of bicalutamide patients. Discontinuations with an AR as the primary reason were reported for 8% of XTANDI patients and 6% of bicalutamide patients.

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RECURRENT mCSPC, LOW VOLUME

NAME Frank AGE 74

OCCUPATION Retired corporate professional

LIFESTYLE I enjoy gardening and reading

MARITAL STATUS Married with 3 children

SUPPORT My oldest son is my caregiver

MEET FRANK

Not an actual patient or patient case; content for illustrative purposes only.

BELIEFS *"I wasn't expecting the cancer to progress, but I understand that progression may not be completely avoided. I'm sure my doctor's recommendations will be helpful."*

ATTITUDES *"I discuss relevant information with my doctor to understand medical advice that's right for me. Keeping a positive attitude about my medical tests has helped me with decision-making."*

GOAL *"My goal is to stay connected with my doctor to help my well-being."*

Not an actual patient testimonial; testimonial based on research of patients with similar disease states and stages discussed on page.

CLINICAL PROFILE

PROSTATE CANCER CLINICAL HISTORY

6 YEARS AGO

- Diagnosis of locally advanced/regional prostate cancer
- **Comorbidity:** arthritis
- **PSA:** 5 ng/mL at initial diagnosis
- **Gleason score:** 7 (4 + 3)
- Treated with external beam radiation therapy

CURRENT CLINICAL EVALUATION

- Diagnosis of recurrent mCSPC with low-volume disease
- **ECOG Performance Status:** 1
- **PSA:** 7.4 ng/mL
- **PET/computed tomography (CT) results:** positive pelvic lymph nodes and 3 metastases in the pelvic bones
- GnRH therapy initiated

Select Safety Information

Adverse Reactions (ARs) (cont'd) In PROSPER, the placebo-controlled study of nonmetastatic CRPC (nmCRPC) patients, Grade 3 or higher ARs were reported in 31% of XTANDI patients and 23% of placebo patients. Discontinuations with an AR as the primary reason were reported for 9% of XTANDI patients and 6% of placebo patients.

In ARCHES, the placebo-controlled study of metastatic CSPC (mCSPC) patients, Grade 3 or higher ARs were reported in 24% of XTANDI-treated patients. Permanent discontinuation due to ARs as the primary reason was reported in 5% of XTANDI patients and 4% of placebo patients.

In EMBARK, the placebo-controlled study of nonmetastatic CSPC (nmCSPC) with high-risk biochemical recurrence (BCR) patients, Grade 3 or higher adverse reactions during the total duration of treatment were reported in 46% of patients treated with XTANDI plus leuprolide, 50% of patients receiving XTANDI as a single agent, and 43% of patients receiving placebo plus leuprolide. Permanent treatment discontinuation due to adverse reactions during the total duration of treatment as the primary reason was reported in 21% of patients treated with XTANDI plus leuprolide, 18% of patients receiving XTANDI as a single agent, and 10% of patients receiving placebo plus leuprolide.

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XTANDI SUPPORT SOLUTIONS®

XTANDI has broad formulary coverage, and **XTANDI Support Solutions** provides access and reimbursement support for your eligible patients prescribed **XTANDI**

SUPPORT FOR PATIENTS, REGARDLESS OF COVERAGE

Medicare Part D

- 99% of Medicare Part D patients with mCSPC or CRPC can access XTANDI without delays due to step-therapy restrictions*[4]
- **XTANDI Support Solutions** can provide information about other resources that might be able to help†
- Formulary status does not imply safety or efficacy of any product. No comparisons should be made

Assistance for Commercial Insurance Patients

Eligibility restrictions, terms, and conditions apply.

The **XTANDI Patient Savings Program**‡ is for eligible patients who have commercial prescription insurance. The Program parameters are as follows:

- Patients may pay as little as $0 per prescription
- Patients will be enrolled in the Program for a 12-month period
- There are no income requirements
- There is a maximum co-pay assistance limit of $7,000 per calendar year

Uninsured

- The **Astellas Patient Assistance Program** provides XTANDI at no cost to patients who meet the program eligibility requirements§

Xtandi (enzalutamide) 40 mg tablets | 80 mg tablets SUPPORT® SOLUTIONS

XtandiSupportSolutions.com
1-855-8XTANDI (1-855-898-2634)
Monday – Friday, 8 AM – 8 PM ET

XTANDI Support Solutions can help your patients obtain XTANDI through our network of specialty pharmacies, help problem-solve financial assistance, and provide educational resources included with prescription delivery

*XTANDI national Medicare coverage status as of February 2023.[4] Percentage is rounded to the nearest whole number and represents the percentage of patients with access to XTANDI as a first-line or a preferred option for the treatment of mCSPC or CRPC. First line indicates that XTANDI is covered without prior indication-specific therapy requirements. Preferred indicates that XTANDI is covered without prior indication-specific therapy requirements, and prior trial with XTANDI may be required before other therapies are covered. Prior authorization may be required. Please check with the health plan to verify coverage details. **FORMULARY STATUS DOES NOT IMPLY SAFETY OR EFFICACY OF ANY PRODUCT. NO COMPARISONS SHOULD BE MADE. A product's placement on a plan formulary involves a variety of factors known only to the applicable plan and is subject to eligibility. Provider communication only—not approved for prescription drug plan member distribution.** Formulary status is not a guarantee. Please verify co-pay, coinsurance, coverage, and updated information with the plan's sponsors. Information subject to change without notice. Astellas and Pfizer do not endorse any individual plans.

†XTANDI Support Solutions has no control over the decisions made by, and does not guarantee support from, independent third parties.

‡By enrolling in the XTANDI Patient Savings Program ("Program"), the patient acknowledges that they currently meet the eligibility criteria and will comply with the following terms and conditions: The Program is for eligible patients with commercial prescription insurance for XTANDI. **The Program is not valid for patients whose prescription claims are reimbursed, in whole or in part, by any state or federal government program, including, but not limited to, Medicaid, Medicare, Medigap, Department of Defense (DoD), Veterans Affairs (VA), TRICARE, Puerto Rico Government Insurance, or any state patient or pharmaceutical assistance program.** Patients who move from commercial insurance to federal or state health insurance will no longer be eligible, and agree to notify the Program of any such change. Patients agree not to seek reimbursement from any health insurance or third party for all or any part of the benefit received by the patient through the Program. This offer is not conditioned on any past, present, or future purchase of XTANDI. This offer is not transferrable and cannot be combined with any other offer, free trial, prescription savings card, or discount. This offer is not health insurance and is only valid for patients in the 50 United States, Washington DC, Puerto Rico, Guam and Virgin Islands. This offer is not valid for cash-paying patients. This Program is void where prohibited by law. No membership fees. It is illegal to sell, purchase, trade, counterfeit, duplicate, or reproduce, or offer to sell, purchase, trade, counterfeit, duplicate or reproduce the card. This offer will be accepted only at participating pharmacies. Certain rules and restrictions apply. Astellas reserves the right to revoke, rescind, or amend this offer without notice.

The XTANDI Patient Savings Program has a maximum co-pay assistance limit of $7,000 per calendar year.

§Program subject to eligibility requirements. Void where prohibited by law.

ASK YOUR SALES REPRESENTATIVE ABOUT SAMPLING AND VOUCHER PROGRAMS TO START NEW PATIENTS ON XTANDI

Select Safety Information

Lab Abnormalities: Lab abnormalities that occurred in ≥ 5% of patients, and more frequently (> 2%) in the XTANDI arm compared to placebo in the pooled, randomized, placebo-controlled studies are hemoglobin decrease, neutrophil count decreased, white blood cell decreased, hyperglycemia, hypermagnesemia, hyponatremia, hyperphosphatemia, and hypercalcemia.

Hypertension: In the combined data from five randomized placebo-controlled clinical trials, hypertension was reported in 14.2% of XTANDI patients and 7.4% of placebo patients. Hypertension led to study discontinuation in < 1% of patients in each arm.

Please see Important Safety Information on pages 14-15 and accompanying Full Prescribing Information in pocket.

Indications and Important Safety Information

Indications

XTANDI is indicated for the treatment of patients with:

- nonmetastatic castration-sensitive prostate cancer (nmCSPC) with biochemical recurrence at high risk for metastasis (high-risk BCR)
- metastatic castration-sensitive prostate cancer (mCSPC)
- castration-resistant prostate cancer (CRPC)

Important Safety Information

Warnings and Precautions

Seizure occurred in 0.6% of patients receiving XTANDI in eight randomized clinical trials. In a study of patients with predisposing factors for seizure, 2.2% of XTANDI-treated patients experienced a seizure. It is unknown whether anti-epileptic medications will prevent seizures with XTANDI. Patients in the study had one or more of the following predisposing factors: use of medications that may lower the seizure threshold, history of traumatic brain or head injury, history of cerebrovascular accident or transient ischemic attack, and Alzheimer's disease, meningioma, or leptomeningeal disease from prostate cancer, unexplained loss of consciousness within the last 12 months, history of seizure, presence of a space occupying lesion of the brain, history of arteriovenous malformation, or history of brain infection. Advise patients of the risk of developing a seizure while taking XTANDI and of engaging in any activity where sudden loss of consciousness could cause serious harm to themselves or others. Permanently discontinue XTANDI in patients who develop a seizure during treatment.

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Hypertension: In the combined data from five randomized placebo-controlled clinical trials, hypertension was reported in 14.2% of XTANDI patients and 7.4% of placebo patients. Hypertension led to study discontinuation in < 1% of patients in each arm.

Drug Interactions

Effect of Other Drugs on XTANDI Avoid coadministration with strong CYP2C8 inhibitors. If coadministration cannot be avoided, reduce the dosage of XTANDI.

Avoid coadministration with strong CYP3A4 inducers. If coadministration cannot be avoided, increase the dosage of XTANDI.

Effect of XTANDI on Other Drugs Avoid coadministration with certain CYP3A4, CYP2C9, and CYP2C19 substrates for which minimal decrease in concentration may lead to therapeutic failure of the substrate. If coadministration cannot be avoided, increase the dosage of these substrates in accordance with their Prescribing Information. In cases where active metabolites are formed, there may be increased exposure to the active metabolites.

Please see accompanying Full Prescribing Information in pocket.

Xtandi®
(enzalutamide)
40 mg tablets | 80 mg tablets




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References: 1. XTANDI [package insert]. Northbrook, IL: Astellas Pharma US, Inc. **2.** Armstrong AJ, Szmulewitz RZ, Petrylak DP, et al. ARCHES: a randomized, phase III study of androgen deprivation therapy with enzalutamide or placebo in men with metastatic hormone-sensitive prostate cancer. J Clin Oncol 2019;37(32):2974-86. **3.** Protocol for: Armstrong AJ, Szmulewitz RZ, Petrylak DP, et al. ARCHES: a randomized, phase III study of androgen deprivation therapy with enzalutamide or placebo in men with metastatic hormone-sensitive prostate cancer. J Clin Oncol 2019;37(32):2974-86. **4.** Astellas. XTANDI. Data on File.

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Pfizer Oncology