Yonsa®
(abiraterone acetate)
125 mg tablets

FOR THE TREATMENT OF mCRPC[1]

HARNESS THE PERFORMANCE OF MICRONIZATION

INDICATION

YONSA® (abiraterone acetate) in combination with methylprednisolone is indicated for the treatment of patients with metastatic castration-resistant prostate cancer (CRPC).

Important Administration Instructions

YONSA® may not be interchangeable with other abiraterone acetate products. To avoid substitution errors and overdose, be aware that YONSA® tablets may have different dosing and food effects than other abiraterone acetate products. Patients receiving YONSA® should also receive a gonadotropin-releasing hormone (GnRH) analog concurrently or should have had bilateral orchiectomy.

IMPORTANT SAFETY INFORMATION

CONTRAINDICATIONS

YONSA® can cause fetal harm and potential loss of pregnancy.

WARNINGS AND PRECAUTIONS

Hypertension, Hypokalemia, and Fluid Retention Due to Mineralocorticoid Excess: YONSA® may cause hypertension, hypokalemia, and fluid retention as a consequence of increased mineralocorticoid levels resulting from CYP17 inhibition. Monitor patients for hypertension, hypokalemia, and fluid retention at least once a month. Control hypertension and correct hypokalemia before and during treatment with YONSA®.

Closely monitor patients whose underlying medical conditions might be compromised by increases in blood pressure, hypokalemia or fluid retention, such as those with heart failure, recent myocardial infarction, cardiovascular disease, or ventricular arrhythmia. The safety of YONSA® in patients with left ventricular ejection fraction < 50% or New York Heart Association (NYHA) Class III or IV heart failure (in Study 1) or NYHA Class II to IV heart failure (in Study 2) was not established because these patients were excluded from these randomized clinical trials.

Please see additional Important Safety Information throughout this document and Full Prescribing Information.

YONSA® — THE FIRST AND ONLY MICRONIZED ABIRATERONE ACETATE[1]

DELIVERING UNIQUE BENEFITS

PROPRIETARY YONSA® MICRONIZATION PROVIDES:

RAPID ABSORPTION

- Increases surface area for rapid dissolution and absorption[2]

LOW 500 MG DOSE

- Four 125 mg tablets plus 4 mg methylprednisolone[1,2]

FLEXIBLE DOSING

- Patients can take YONSA® with or without food[1,3]

Learn more about the micronization process at www.YonsaRx.com

IMPORTANT SAFETY INFORMATION, CONTINUED

WARNINGS AND PRECAUTIONS

Adrenocortical Insufficiency (AI): AI was reported in patients receiving abiraterone acetate in combination with corticosteroid, following an interruption of daily steroids and/or with concurrent infection or stress. Monitor patients for symptoms and signs of AI, particularly if patients are withdrawn from corticosteroids, have corticosteroid dose reductions, or experience unusual stress. Symptoms and signs of AI may be masked by adverse reactions associated with mineralocorticoid excess seen in patients treated with YONSA®. Perform appropriate tests, if indicated, to confirm AI. Increased dosages of corticosteroids may be used before, during, and after stressful situations.

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Yonsa® (abiraterone acetate) 125 mg tablets

THE ONLY ABIRATERONE ACETATE WITH NO FOOD RESTRICTIONS[1,4]

YONSA® Provides Flexibility That Patients May Value[1]

Patients have the option to take YONSA®, in combination with methylprednisolone, with or without food.[1,3]

YONSA® is FDA Approved to Treat Metastatic Castration-Resistant Prostate Cancer (mCRPC) With a 500 mg Dose[1]

YONSA® 500 mg (four 125 mg tablets) is administered orally once daily in combination with oral methylprednisolone (4 mg per dose twice daily).[1]

DOSE MODIFICATION[1]

For patients with baseline moderate hepatic impairment (Child-Pugh Class B), reduce the YONSA® starting dose to 125 mg once daily.

For patients who develop hepatotoxicity during treatment, hold YONSA® until recovery. Retreatment may be initiated at a reduced dose. YONSA® should be discontinued if patients develop severe hepatotoxicity.

Pills not of actual size

IMPORTANT SAFETY INFORMATION, CONTINUED

WARNINGS AND PRECAUTIONS

Hepatotoxicity: In postmarketing experience, there have been abiraterone acetate-associated severe hepatic toxicity, including fulminant hepatitis, acute liver failure and deaths. Measure serum transaminases (ALT and AST) and bilirubin levels prior to starting treatment with YONSA®, every two weeks for the first three months of treatment and monthly thereafter. In patients with baseline moderate hepatic impairment receiving a reduced YONSA® dose of 125 mg, measure ALT, AST, and bilirubin prior to the start of treatment, every week for the first month, every two weeks for the following two months of treatment and monthly thereafter. Promptly measure serum total bilirubin, AST, and ALT if clinical symptoms or signs suggestive of hepatotoxicity develop. Elevations of AST, ALT, or bilirubin from the patient's baseline should prompt more frequent monitoring. If at any time AST or ALT rise above five times the ULN, or the bilirubin rises above three times the ULN, interrupt YONSA® treatment and closely monitor liver function.

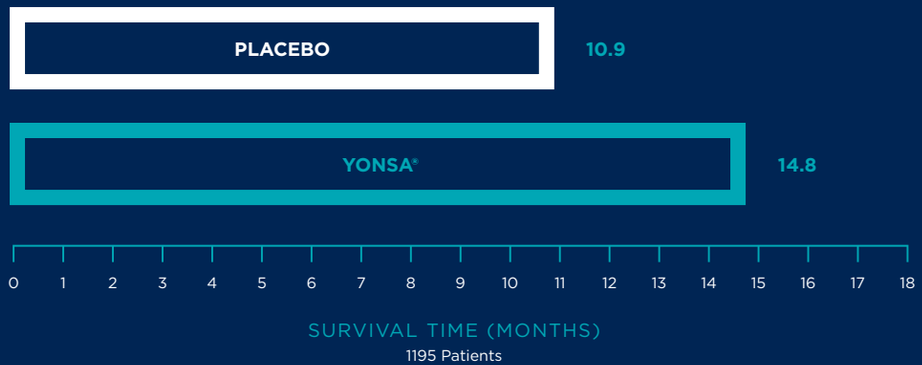
Please see additional Important Safety Information throughout this document and Full Prescribing Information.

IMPROVING SURVIVAL WITH YONSA®

OVERALL SURVIVAL

In patients with mCRPC who received prior docetaxel chemotherapy:

SIGNIFICANT IMPROVEMENT IN OVERALL SURVIVAL VS PLACEBO[1]
(14.8 VS 10.9 MONTHS, RESPECTIVELY, *P*<.0001)*



*In a randomized, placebo-controlled, multicenter phase 3 clinical trial, patients with mCRPC who had received prior docetaxel chemotherapy received abiraterone acetate at a dose equivalent to YONSA® 500 mg once daily in combination with methylprednisolone twice daily (N=797), or placebo (N=398).

IMPORTANT SAFETY INFORMATION, CONTINUED

WARNINGS AND PRECAUTIONS, CONTINUED

Hepatotoxicity (continued): Re-treatment with YONSA® at a reduced dose level may take place only after return of liver function tests to the patient's baseline or to AST and ALT less than or equal to 2.5X ULN and total bilirubin less than or equal to 1.5X ULN.

Permanently discontinue treatment with abiraterone acetate for patients who develop a concurrent elevation of ALT greater than 3X ULN and total bilirubin greater than 2X ULN in the absence of biliary obstruction or other causes responsible for the concurrent elevation.

The safety of YONSA® re-treatment of patients who develop AST or ALT greater than or equal to 20X ULN and/or bilirubin greater than or equal to 10X ULN is unknown.

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Yonsa® (abiraterone acetate) 125 mg tablets

EXTENDING TIME WITH YONSA®

INCREASING TIME TO CHEMOTHERAPY[1]

For patients who had not received prior cytotoxic chemotherapy:

FIFTY PERCENT LONGER TIME TO CHEMOTHERAPY VS PLACEBO
(25.2 MONTHS VS 16.8 MONTHS, RESPECTIVELY, *P*<.0001)[1]*

50% LONGER TIME TO CHEMOTHERAPY

YONSA® PROVIDES SIMILAR BIOAVAILABILITY TO THE 1000 MG DOSE OF ABIRATERONE ACETATE PLUS CORTICOSTEROID[2]

*In a study of 1088 patients with mCRPC who had not received prior cytotoxic chemotherapy, subjects received abiraterone acetate at a dose equivalent to YONSA® 500 mg once daily in combination with a different corticosteroid twice daily (N=546) or placebo once daily with corticosteroid twice daily (N=542).

SAFETY PROFILE

Two randomized placebo-controlled, multicenter clinical trials enrolled patients who had metastatic castration-resistant prostate cancer who were using a gonadotropin-releasing hormone (GnRH) agonist or were previously treated with orchiectomy. In both Study 1 and Study 2 abiraterone acetate was administered at a dose equivalent to 500 mg of YONSA daily in combination with a different corticosteroid twice daily in the active treatment arms. Placebo plus corticosteroid was given to control patients.

The most common adverse drug reactions (>10%) reported in the two randomized clinical trials that occurred more commonly (>2%) in the abiraterone acetate arm were fatigue, joint swelling or discomfort, edema, hot flush, diarrhea, vomiting, cough, hypertension, dyspnea, urinary tract infection and contusion.

The most common laboratory abnormalities (>20%) reported in the two randomized clinical trials that occurred more commonly (≥2%) in the abiraterone acetate arm were anemia, elevated alkaline phosphatase, hypertriglyceridemia, lymphopenia, hypercholesterolemia, hyperglycemia, elevated AST, hypophosphatemia, elevated ALT and hypokalemia.

YONSA SUPPORT™ PROGRAMS PROVIDE A SIMPLE PATH TO SERVICES FOR ELIGIBLE PATIENTS

Benefits Investigations (BI) and Prior Authorization (PA) Assistance

YONSA SUPPORT™ will initiate a BI of the patient's insurance coverage for YONSA® and/or obtain information on any associated PA requests.

Co-pay Program* (eligible commercially insured patients)

- Eligible patients pay as little as $10 for YONSA®† with co-pay card
- YONSA SUPPORT™ will determine a patient's eligibility and enroll him/her into the Co-pay Program for YONSA®

*See www.YonsaRx.com for details. $5,000 maximum program benefit per fill and $12,000 maximum program benefit per calendar year. Not valid for patients without commercial insurance coverage or if prescription is paid for by any state or federally funded healthcare program, including but not limited to Medicare, Medicaid, VA, DOD, or TRICARE. Available to US, Guam, Virgin Islands, or Puerto Rico residents only. See Full Terms and Conditions at YonsaRx.com.

†Subject to terms and conditions. Must be enrolled in YONSA SUPPORT™ to qualify.

IMPORTANT SAFETY INFORMATION, CONTINUED

ADVERSE REACTIONS

The most common adverse reactions (≥10%) are fatigue, joint swelling or discomfort, edema, hot flush, diarrhea, vomiting, cough, hypertension, dyspnea, urinary tract infection and contusion.

The most common laboratory abnormalities (>20%) are anemia, elevated alkaline phosphatase, hypertriglyceridemia, lymphopenia, hypercholesterolemia, hyperglycemia, elevated AST, hypophosphatemia, elevated ALT and hypokalemia.

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Patient Assistance Program (PAP)

For eligible patients with noncommercial insurance: If applicable, YONSA SUPPORT™ will research alternate forms of funding (including PAP) and, if the patient is eligible, help with enrollment.*

Claim Denial Assistance

YONSA SUPPORT™ will, if applicable, initiate review and research of a patient's denied claim.

PERSONAL, ONE-ON-ONE ASSISTANCE FROM A CASE MANAGER

CLAIM DENIAL ASSISTANCE

ENROLL YOUR PATIENTS IN YONSA SUPPORT™ TODAY

- Simply fill in a single patient enrollment form available at www.YonsaRx.com
- If you have questions, please contact YONSA SUPPORT™ at 1-855-44YONSA (1-855-449-6672)

*Subject to terms and conditions. Must be enrolled in YONSA SUPPORT™ to qualify.

IMPORTANT SAFETY INFORMATION, CONTINUED

DRUG INTERACTIONS

Based on *in vitro* data, YONSA® is a substrate of CYP3A4. In a drug interaction trial, co-administration of rifampin, a strong CYP3A4 inducer, decreased exposure of abiraterone by 55%. Avoid concomitant strong CYP3A4 inducers during YONSA® treatment. If a strong CYP3A4 inducer must be co-administered, increase the YONSA® dosing frequency only during the co-administration period.

Abiraterone is an inhibitor of the hepatic drug-metabolizing enzymes CYP2D6 and CYP2C8. Avoid coadministration of abiraterone acetate with substrates of CYP2D6 with a narrow therapeutic index (e.g., thioridazine). If alternative treatments cannot be used, exercise caution and consider a dose reduction of the concomitant CYP2D6 substrate drug.

In a CYP2C8 drug-drug interaction trial in healthy subjects, the AUC of pioglitazone (CYP2C8 substrate) was increased by 46% when pioglitazone was given together with an abiraterone acetate single dose equivalent to YONSA® 500 mg. Therefore, patients should be monitored closely for signs of toxicity related to a CYP2C8 substrate with a narrow therapeutic index if used concomitantly with abiraterone acetate.

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INDICATION

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IMPORTANT SAFETY INFORMATION

CONTRAINDICATIONS

YONSA® can cause fetal harm and potential loss of pregnancy.

WARNINGS AND PRECAUTIONS

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Re-treatment with YONSA® at a reduced dose level may take place only after return of liver function tests to the patient's baseline or to AST and ALT less than or equal to 2.5X ULN and total bilirubin less than or equal to 1.5X ULN.

Permanently discontinue treatment with abiraterone acetate for patients who develop a concurrent elevation of ALT greater than 3 x ULN and total bilirubin greater than 2 x ULN in the absence of biliary obstruction or other causes responsible for the concurrent elevation.

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USE IN SPECIFIC POPULATIONS

- **Females and Males of Reproductive Potential: Advise male patients with female partners of reproductive potential to use effective contraception.**
- Do not use YONSA® in patients with baseline severe hepatic impairment (Child-Pugh Class C).

Please see Full Prescribing Information.

Yonsa®
(abiraterone acetate)
125 mg tablets

YONSA® IS THE FIRST AND ONLY MICRONIZED FORMULATION OF ABIRATERONE ACETATE[1]

ONLY YONSA® DELIVERS:

INNOVATION

- Proprietary micronization, allowing rapid dissolution and absorption[2]
- 500 mg dose in combination with oral methylprednisolone[1,2]

EFFICACY

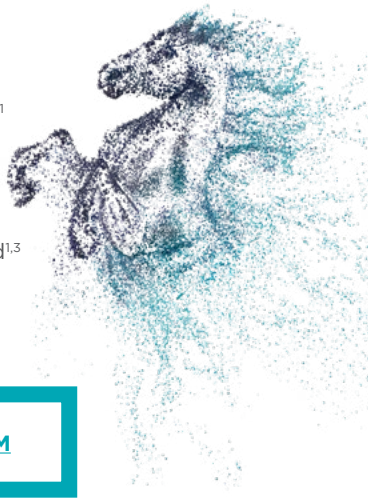
- Significant improvements in overall survival vs placebo[1]
- Time to chemotherapy significantly longer than with placebo[1]
- Similar bioavailability to the 1000 mg dose of abiraterone acetate plus corticosteroid[2]

FLEXIBILITY

- The option for patients to take YONSA® with or without food[1,3]

SERVICES

- Comprehensive patient support programs



LEARN MORE AT WWW.YONSARX.COM

IMPORTANT SAFETY INFORMATION, CONTINUED

USE IN SPECIFIC POPULATIONS

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References: 1. YONSA® [prescribing information]. Cranbury, NJ: Sun Pharmaceutical Industries, Inc; May 2018. **2.** Goldwater R, Hussaini A, Bosch B, Nemeth P. Comparison of a novel formulation of abiraterone acetate vs. the originator formulation in healthy male subjects: two randomized, open-label, crossover studies. *Clin Pharmacokinet.* 2017;56:803–813. **3.** Hussaini A, Olszanski AJ, Stein CA, Bosch B, Nemeth P. Impact of an alternative steroid on the relative bioavailability and bioequivalence of a novel versus the originator formulation of abiraterone acetate. *Cancer Chemo Pharmacol.* 2017;80(3):479–486. **4.** Zytiga® [prescribing information]. Horsham, PA: Janssen Biotech, Inc; March 2018.

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