Yonsa®
(abiraterone acetate)
125 mg tablets

TRICARE AND YONSA®

Tricare has designated YONSA® as the Department of Defense's Preferred CYP-17 Inhibitor agent on the Uniform/TRICARE Formulary.[1] All new patients and current users of ZYTIGA® (abiraterone acetate)/generics are required to try YONSA® first, unless they have already tried YONSA® or they have or have had a contraindication, inadequate response, or adverse reaction to YONSA® that is not expected to occur with the requested agent.[1]

YONSA®, in combination with methylprednisolone, is the first and only micronized formulation of abiraterone acetate for the treatment of metastatic castration-resistant prostate cancer (CRPC) with a Tier 1 co-pay.[2]

PROPRIETARY YONSA® MICRONIZATION PROVIDES:

RAPID ABSORPTION
Increases surface area for rapid dissolution and absorption[3]

LOW 500 MG DOSE
Four 125 mg tablets plus 4 mg methylprednisolone[2,3]

FLEXIBLE DOSING
Patients can take YONSA® with or without food[2,4]

The Tricare and Sun partnership offers the military another option for mCRPC therapy.

Pills not of actual size

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 on reverse side and accompanying Full Prescribing Information.

IMPORTANT SAFETY INFORMATION, CONTINUED

WARNINGS AND PRECAUTIONS, CONTINUED

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.

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.

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.

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.

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.

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 additional Important Safety Information on reverse side and accompanying Full Prescribing Information.

References: 1. The official website of the Military Health System. DoD Pharmacy & Therapeutic Committee. https://health.mil/About-MHS/ OASDHA/Defense-Health-Agency/Operations/Pharmacy-Division/DoD-Pharmacy-and-Therapeutics-Committee. February 2019. Accessed July 2, 2019. **2.** YONSA® [prescribing information]. Cranbury, NJ: Sun Pharmaceutical Industries, Inc; May 2018. **3.** 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. **4.** 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.

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