

# YONSA SUPPORT<sup>®</sup> Resource Guide

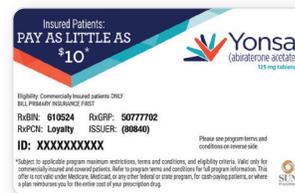
Help your eligible patients receive YONSA<sup>®</sup>

Please contact your YONSA<sup>®</sup> sales representative with any questions about the application process or call **YONSA SUPPORT<sup>®</sup>** at **1-855-44YONSA (1-855-449-6672)** Monday-Friday, 8 AM-8 PM EST.

## Co-Pay Card Program

The **YONSA<sup>®</sup> Co-Pay Program** helps eligible, commercially insured patients 18 years or older access their YONSA<sup>®</sup> prescriptions.\*

\*Subject to Terms and Conditions below.



## Patient Assistance Program

Patients who are underinsured or uninsured may be eligible to receive free medication.† To get your patients started with the Patient Assistance Program, simply **complete the YONSA SUPPORT<sup>®</sup> Patient Assistance Program Application, which is available at YONSARx.com.**

†Income documentation is required.

## Prior Authorization Assistance

Powered by **CoverMyMeds<sup>®</sup>**

Sun Pharma and CoverMyMeds are working together to expedite the prior authorization process to help your patients receive their YONSA<sup>®</sup> therapy as prescribed.

**For more information, contact CoverMyMeds at 1-866-452-5017.**

### YONSA<sup>®</sup> Co-Pay Terms and Conditions

To participate in the YONSA<sup>®</sup> Co-Pay Program ("Program"), you must present this card, along with a valid prescription for YONSA<sup>®</sup>, to your pharmacist. Patients with commercial health insurance who qualify to participate can pay as little as \$10 per month for one YONSA<sup>®</sup> prescription. The maximum benefit allowed under the Program is \$12,000 in each calendar year and no more than \$5,000 for each individual prescription filled. Enrollment is subject to the Eligibility Rules and Terms and Conditions, stated below. If you have any questions regarding Eligibility, the Terms and Conditions, or to discontinue participation, please call 1-855-984-6307 (8:00 am-8:00 pm EST, Monday-Friday).

#### Eligibility Rules

- To participate in this Program, you must have commercial health insurance and be a resident of the United States (excluding patients residing in Massachusetts, Puerto Rico, Guam, or the Virgin Islands)
- The following patients are *ineligible* for this Program:
  - Patients covered by Medicare, Medicaid, TRICARE, the Veterans Affairs, the Department of Defense, or have prescription drug coverage under any other federal or state program
  - Patients with no insurance
  - Patients who have coverage that imposes no co-pay or co-insurance charge (*i.e.*, insurance covering the full cost of YONSA<sup>®</sup>)
  - If the FDA approves a therapeutically equivalent Rx drug, or if an OTC drug containing abiraterone acetate (the active ingredient in YONSA<sup>®</sup>) becomes available, the Program will exclude patients residing in California

#### Terms and Conditions

- You agree to not seek any reimbursement for all or any part of the co-pay assistance received through the Program. By using this card, you are certifying that you understand the Eligibility Rules and Terms and Conditions, that you have responded truthfully to questions when activating the card, and that you will disclose and report your receipt of any Program benefits to your insurer, health plan, or any third party that pays or reimburses you for the cost of medications, if required
- This offer may be rescinded, revoked, or cancelled at any time without further notice, and the rules may be amended at any time without further notice
- If a patient obtains coverage from such a government program after enrolling in this Program, he/she will not be eligible to continue in the Program

#### Disclosures

- This Program is not insurance
- The Program is void where prohibited by law, taxed, or restricted. Any benefit provided is non-transferable, and cannot be combined with any other program, free trial, discount, prescription savings card, or other offer. No purchase, other than for a YONSA<sup>®</sup> prescription, is required to participate
- Personal data that you provide to the Program may be collected, analyzed, and shared with the Program sponsor for market research and other lawful purposes, but only in aggregated and de-identified form

**Please see Important Safety Information on reverse, and accompanying Full Prescribing Information.**

## INDICATION

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

## IMPORTANT SAFETY INFORMATION

### WARNINGS AND PRECAUTIONS

#### Hypertension, Hypokalemia, and Fluid Retention Due to Mineralocorticoid Excess:

YONSA® may cause hypertension, hypokalemia, and fluid retention due to increased mineralocorticoid levels resulting from CYP17 inhibition. Monitor patients 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. In postmarketing experience, QT prolongation and Torsades de Pointes have been observed in patients who develop hypokalemia while taking abiraterone acetate.

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 evaluated because these patients were excluded from randomized clinical trials.

**Adrenocortical Insufficiency:** Adrenocortical insufficiency (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 has been abiraterone acetate-associated severe hepatic toxicity, including reports of 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 upper limit of normal (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 has not been evaluated.

### Increased Fractures and Mortality in Combination with Radium

**Ra 223 Dichloride:** YONSA® plus methylprednisolone is not recommended for use in combination with radium Ra 223 dichloride outside of clinical trials.

Increased incidences of fractures (28.6% vs 11.4%) and deaths (38.5% vs 35.5%) have been observed in patients who received abiraterone acetate plus a corticosteroid in combination with radium Ra 223 dichloride compared to patients who received placebo in combination with abiraterone acetate plus a corticosteroid.

**Embryo-Fetal Toxicity:** The safety and efficacy of YONSA® have not been established in females. Based on animal reproductive studies and mechanism of action, YONSA® 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 YONSA® and for 3 weeks after the final dose of YONSA®.

Females who are pregnant or may be pregnant should not handle YONSA® tablets if broken, crushed, or damaged without protection, eg, gloves.

**Hypoglycemia:** Severe hypoglycemia has been reported when abiraterone acetate was administered to patients with pre-existing diabetes receiving medications containing thiazolidinediones (including pioglitazone) or repaglinide. Monitor blood glucose in patients with diabetes during and after discontinuation of treatment with abiraterone acetate. Assess if antidiabetic drug dosage needs to be adjusted to minimize the risk of hypoglycemia.

## 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

**Drugs that Inhibit or Induce CYP3A4 Enzymes:** 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.

**Effects of Abiraterone on Drug-Metabolizing Enzymes:** Abiraterone is an inhibitor of the hepatic drug-metabolizing enzymes CYP2D6 and CYP2C8. Avoid co-administration of abiraterone acetate with substrates of CYP2D6 with a narrow therapeutic index (eg, 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.

**Please see accompanying Full Prescribing Information.**