

<p><b>PATIENT INFORMATION</b> YONSA® (Yon-suh) (abiraterone acetate) tablets</p>
<p><b>What is YONSA?</b> YONSA is a prescription medicine that is used along with methylprednisolone. YONSA is used to treat men with prostate cancer that has spread to other parts of the body and no longer responds to medical or surgical treatment that lowers testosterone. It is not known if YONSA is safe and effective in females or children.</p>
<p><b>Before taking YONSA, tell your healthcare provider about all of your medical conditions, including if you:</b></p> <ul style="list-style-type: none"><li>• have heart problems</li><li>• have liver problems</li><li>• have diabetes</li><li>• have a history of adrenal problems</li><li>• have a history of pituitary problems</li><li>• are receiving any other treatment for prostate cancer</li><li>• are pregnant or plan to become pregnant. YONSA can cause harm to your unborn baby and loss of pregnancy (miscarriage). Females who are or may become pregnant should not handle YONSA tablets if broken, crushed, or damaged without protection, such as gloves.</li><li>• have a partner who is pregnant or may become pregnant.<ul style="list-style-type: none"><li>◦ Males who have female partners who are able to become pregnant should use effective birth control (contraception) during treatment with YONSA and for 3 weeks after the last dose of YONSA.</li></ul></li><li>• are breastfeeding or plan to breastfeed. It is not known if YONSA passes into your breastmilk.</li></ul> <p><b>Tell your healthcare provider about all the medicines you take or treatments you receive,</b> including prescription and over-the-counter medicines, vitamins, and herbal supplements. YONSA can interact with many other medicines. You should not start or stop any medicine before you talk with the healthcare provider that prescribed YONSA. Know the medicines you take. Keep a list of them with you to show to your healthcare provider and pharmacist when you get a new medicine.</p>
<p><b>How should I take YONSA?</b></p> <ul style="list-style-type: none"><li>• Take YONSA and methylprednisolone exactly as your healthcare provider tells you.</li><li>• Take your prescribed dose of YONSA 1 time a day. Take your prescribed dose of methylprednisolone 2 times a day.</li><li>• YONSA contains abiraterone acetate. <b>YONSA and other medicines that contain abiraterone acetate may not be the same.</b><ul style="list-style-type: none"><li>◦ <b>Do not</b> switch between YONSA and other medicines that contain abiraterone acetate unless your healthcare provider tells you to.</li><li>◦ Follow your healthcare provider's instructions carefully if you are switching between YONSA and another medicine that contains abiraterone acetate.</li><li>◦ <b>Do not take</b> YONSA and other medicines that contain abiraterone acetate on the same day.</li><li>◦ If you do not have enough YONSA to take your full dose or if you have any other questions about YONSA, talk with your healthcare provider or pharmacist.</li></ul></li><li>• Your healthcare provider may change your dose of YONSA if needed.</li><li>• <b>Do not change or stop taking your prescribed dose of YONSA or methylprednisolone without talking with your healthcare provider first.</b></li><li>• Take YONSA with or without food.</li><li>• Swallow YONSA tablets whole. Do not crush or chew tablets.</li><li>• Take YONSA with water.</li><li>• If you miss a dose of YONSA or methylprednisolone, take your prescribed dose the following day. If you miss more than 1 dose, tell your healthcare provider right away.</li><li>• If you are receiving gonadotropin-releasing hormone (GnRH) therapy, you should continue your therapy during treatment with YONSA and methylprednisolone.</li><li>• If you take too much YONSA, call your healthcare provider or go to the nearest hospital emergency room right away.</li><li>• Your healthcare provider will do blood tests to check for side effects.</li></ul>
<p><b>What are the possible side effects of YONSA?</b> <b>YONSA may cause serious side effects, including:</b></p> <ul style="list-style-type: none"><li>• <b>High blood pressure (hypertension), low blood potassium levels (hypokalemia), fluid retention (edema), and irregular heartbeats can happen during treatment with YONSA.</b> This can be life threatening. To decrease the chance of this happening, you must take methylprednisolone with YONSA exactly as your healthcare provider tells you. Your healthcare</li></ul>

<p>provider will check your blood pressure, do blood tests to check your potassium levels, and check for any signs and symptoms of fluid retention every month during treatment with YONSA.</p> <p><b>Tell your healthcare provider if you get any of the following symptoms:</b></p> <ul style="list-style-type: none"><li>◦ dizziness</li><li>◦ fast or irregular heartbeats</li><li>◦ feel faint or lightheaded</li><li>◦ headache</li><li>◦ confusion</li><li>◦ muscle weakness</li><li>◦ pain in your legs</li><li>◦ swelling in your legs or feet</li></ul> <ul style="list-style-type: none"><li>• <b>Adrenal problems</b> may happen if you stop taking methylprednisolone, get an infection, or are under stress.</li><li>• <b>Severe liver problems.</b> You may develop changes in liver function blood tests. Your healthcare provider will do blood tests to check your liver before treatment with YONSA and during treatment with YONSA. Liver failure may occur, which can lead to death. Tell your healthcare provider right away if you notice any of the following changes:<ul style="list-style-type: none"><li>◦ yellowing of the skin or eyes</li><li>◦ darkening of the urine</li><li>◦ severe nausea or vomiting</li></ul></li><li>• <b>Increased risk of bone fracture and death</b> when YONSA and methylprednisolone, is used in combination with a type of radiation called radium Ra 223 dichloride. Tell your healthcare provider about any other treatments you are taking for prostate cancer.</li><li>• <b>Severe low blood sugar (hypoglycemia).</b> Severe low blood sugar with YONSA can happen in people who have diabetes and take certain antidiabetic medicines. You and/or your healthcare provider should check your blood sugar levels regularly during treatment with YONSA and after you stop treatment. Your healthcare provider may also need to change the dose of your antidiabetic medicines. Signs and symptoms of low blood sugar may include:<ul style="list-style-type: none"><li>• headache</li><li>• drowsiness</li><li>• weakness</li><li>• dizziness</li><li>• confusion</li><li>• irritability</li><li>• hunger</li><li>• fast heartbeat</li><li>• sweating</li><li>• feeling jittery</li></ul></li></ul> <p><b>The most common side effects of YONSA include:</b></p> <ul style="list-style-type: none"><li>• feeling weak or tired</li><li>• joint swelling or pain</li><li>• swelling in your legs or feet</li><li>• hot flushes</li><li>• diarrhea</li><li>• vomiting</li><li>• cough</li><li>• high blood pressure</li><li>• shortness of breath</li><li>• urinary tract infection</li><li>• bruising</li><li>• low red blood cells (anemia)</li><li>• high blood cholesterol and triglycerides</li><li>• high blood sugar levels</li><li>• changes in liver function blood tests</li><li>• low blood potassium levels</li><li>• certain other abnormal blood tests</li></ul> <p>YONSA may cause fertility problems in males, which may affect the ability to father children. Talk to your healthcare provider if you have concerns about fertility.</p> <p>These are not all the possible side effects of YONSA. Call your healthcare provider for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.</p> <p><b>How should I store YONSA?</b></p> <ul style="list-style-type: none"><li>• Store YONSA at room temperature between 68°F to 77°F (20°C to 25°C).</li></ul> <p><b>Keep YONSA and all medicines out of the reach of children.</b></p> <p><b>General information about the safe and effective use of YONSA.</b> Medicines are sometimes prescribed for purposes other than those listed in a Patient Information leaflet. Do not use YONSA for a condition for which it was not prescribed. Do not give YONSA to other people, even if they have the same symptoms that you have. It may harm them. You can ask your healthcare provider or pharmacist for information about YONSA that is written for health professionals.</p> <p><b>What are the ingredients in YONSA?</b> <b>Active ingredient:</b> abiraterone acetate. <b>Inactive ingredients:</b> lactose monohydrate, microcrystalline cellulose, croscarmellose sodium, sodium lauryl sulfate, sodium stearyl fumarate, butylated hydroxyanisole, butylated hydroxytoluene.</p> <p>Manufactured for Sun Pharmaceutical Industries Limited Distributed by Sun Pharmaceutical Industries, Inc. Cranbury, NJ 08512 YONSA is a registered trademark of Sun Pharmaceutical Industries Limited © 2022 Sun Pharmaceutical Industries Limited All rights reserved. For more information, call Sun Pharmaceutical Industries, Inc at 1-800-818-4555 or go to <a href="http://www.yonsarx.com">www.yonsarx.com</a></p>
<p>This Patient Information has been approved by the Revised: 2022 July U.S. Food and Drug Administration</p>