

PATIENT INFORMATION abiraterone acetate tablets
<p>What is abiraterone acetate? Abiraterone acetate is a prescription medicine that is used along with methylprednisolone. Abiraterone acetate 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 abiraterone acetate is safe and effective in females or children.</p>
<p>Before taking abiraterone acetate, tell your healthcare provider about all of your medical conditions, including if you:</p> <ul style="list-style-type: none"> • have heart problems • have liver problems • have diabetes • have a history of adrenal problems • have a history of pituitary problems • are receiving any other treatment for prostate cancer • are pregnant or plan to become pregnant. Abiraterone acetate can cause harm to your unborn baby and loss of pregnancy (miscarriage). Females who are or may become pregnant should not handle abiraterone acetate tablets if broken, crushed, or damaged without protection, such as gloves. • have a partner who is pregnant or may become pregnant. <ul style="list-style-type: none"> ◦ Males who have female partners who are able to become pregnant should use effective birth control (contraception) during treatment with abiraterone acetate and for 3 weeks after the last dose of abiraterone acetate. • are breastfeeding or plan to breastfeed. It is not known if abiraterone acetate passes into your breastmilk. <p>Tell your healthcare provider about all the medicines you take or treatments you receive, including prescription and over-the-counter medicines, vitamins, and herbal supplements. abiraterone acetate can interact with many other medicines.</p> <p>You should not start or stop any medicine before you talk with the healthcare provider that prescribed abiraterone acetate.</p> <p>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>How should I take abiraterone acetate?</p> <ul style="list-style-type: none"> • Take abiraterone acetate and methylprednisolone exactly as your health care provider tells you. • Take your prescribed dose of abiraterone acetate 1 time a day. Take your prescribed dose of methylprednisolone 2 times a day. • Abiraterone acetate and other medicines that contain abiraterone acetate may not be the same. <ul style="list-style-type: none"> ◦ Do not switch between abiraterone acetate and other medicines that contain abiraterone acetate unless your healthcare provider tells you to. ◦ Follow your healthcare provider's instructions carefully if you are switching between abiraterone acetate and another medicine that contains abiraterone acetate. ◦ Do not take abiraterone acetate and other medicines that contain abiraterone acetate on the same day. ◦ If you do not have enough abiraterone acetate to take your full dose or if you have any other questions about abiraterone acetate, talk with your healthcare provider or pharmacist. • Your healthcare provider may change your dose of abiraterone acetate if needed. • Do not change or stop taking your prescribed dose of abiraterone acetate or methylprednisolone without talking with your healthcare provider first. • Take abiraterone acetate with or without food. • Swallow abiraterone acetate tablets whole. Do not crush or chew tablets. • Take abiraterone acetate with water. • If you miss a dose of abiraterone acetate or methylprednisolone, take your prescribed dose the following day. If you miss more than 1 dose, tell your healthcare provider right away. • If you are receiving gonadotropin-releasing hormone (GnRH) therapy, you should continue your therapy during treatment with abiraterone acetate and methylprednisolone. • If you take too much abiraterone acetate, call your healthcare provider or go to the nearest hospital emergency room right away. • Your healthcare provider will do blood tests to check for side effects.
<p>What are the possible side effects of abiraterone acetate? abiraterone acetate may cause serious side effects, including:</p> <ul style="list-style-type: none"> • High blood pressure (hypertension), low blood potassium levels (hypokalemia), fluid retention (edema), and irregular heartbeats can happen during treatment with abiraterone acetate. This can be life threatening. To decrease the chance of this happening, you must take methylprednisolone with abiraterone acetate exactly as your healthcare provider tells you. Your healthcare 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 abiraterone acetate. <p>Tell your healthcare provider if you get any of the following symptoms:</p> <ul style="list-style-type: none"> ◦ dizziness ◦ fast or irregular heartbeats ◦ feel faint or lightheaded ◦ headache ◦ confusion ◦ muscle weakness ◦ pain in your legs ◦ swelling in your legs or feet <ul style="list-style-type: none"> • Adrenal problems may happen if you stop taking methylprednisolone, get an infection, or are under stress. • Severe liver problems. You may develop changes in liver function blood tests. Your healthcare provider will do blood tests to check your liver before treatment with abiraterone acetate and during treatment with abiraterone acetate. 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"> ◦ yellowing of the skin or eyes ◦ darkening of the urine ◦ severe nausea or vomiting • Increased risk of bone fracture and death when abiraterone acetate 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.

<ul style="list-style-type: none"> • Severe low blood sugar (hypoglycemia). Severe low blood sugar with abiraterone acetate 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 abiraterone acetate 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"> • headache • drowsiness • weakness • dizziness • confusion • irritability • hunger • fast heartbeat • sweating • feeling jittery <p>The most common side effects of abiraterone acetate include:</p> <ul style="list-style-type: none"> • feeling weak or tired • joint swelling or pain • swelling in your legs or feet • hot flushes • diarrhea • vomiting • cough • high blood pressure • shortness of breath • urinary tract infection • bruising • low red blood cells (anemia) • high blood cholesterol and triglycerides • high blood sugar levels • changes in liver function blood tests • low blood potassium levels • certain other abnormal blood tests
<p>Abiraterone acetate 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 abiraterone acetate. Call your healthcare provider for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.</p>
<p>How should I store abiraterone acetate?</p> <ul style="list-style-type: none"> • Store abiraterone acetate at room temperature between 68°F to 77°F (20°C to 25°C). <p>Keep abiraterone acetate and all medicines out of the reach of children.</p>
<p>General information about the safe and effective use of abiraterone acetate.</p> <p>Medicines are sometimes prescribed for purposes other than those listed in a Patient Information leaflet. Do not use abiraterone acetate for a condition for which it was not prescribed. Do not give abiraterone acetate to other people, even if they have the same symptoms that you have. It may harm them.</p> <p>You can ask your healthcare provider or pharmacist for information about abiraterone acetate that is written for health professionals.</p>
<p>What are the ingredients in abiraterone acetate?</p> <p>Active ingredient: abiraterone acetate. Inactive ingredients: lactose monohydrate, microcrystalline cellulose, croscarmellose sodium, sodium lauryl sulfate, sodium stearyl fumarate, butylated hydroxyanisole, butylated hydroxytoluene.</p> <p>Marketed by: GSMS, Inc. Camarillo, CA 93012 USA</p>

This Patient Information has been approved by the Revised: 2022 July
 U.S. Food and Drug Administration