ZYTIGA® (abiraterone acetate) What Are the Possible Side Effects of ZYTIGA?

SUMMARY

The following content from the ZYTIGA PATIENT INFORMATION may be helpful to address your question:

ZYTIGA may cause serious side effects including:1

- High blood pressure (hypertension), low blood potassium levels (hypokalemia), fluid retention (edema), and irregular heartbeats can happen during treatment with ZYTIGA.
 - This can be life threatening. To decrease the chance of this happening, you must take prednisone with ZYTIGA 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 ZYTIGA.

Tell your healthcare provider if you get any of the following symptoms:1

- Dizziness
- Fast or irregular heartbeats
- Feel faint or lightheaded
- Headache
- o Confusion
- Muscle weakness
- Pain in your legs
- Swelling in your legs or feet

Other possible side effects include:1

- **Adrenal problems** may happen if you stop taking prednisone, 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 ZYTIGA and during treatment with ZYTIGA. Liver failure may occur, which can lead to death. Tell your healthcare provider right away if you notice any of the following changes:
 - Yellowing of the skin or eyes
 - Darkening of the urine
 - Severe nausea or vomiting
- **Increased risk of bone fracture and death** when ZYTIGA and prednisone or prednisolone, 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.
- Severe low blood sugar (hypoglycemia)
 - Severe low blood sugar with ZYTIGA can happen in people who have diabetes and take certain antidiabetic medicines. You and your healthcare provider should check your blood sugar levels regularly during treatment with ZYTIGA 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:
 - Headache
 - Drowsiness
 - Weakness

- Dizziness
- Confusion
- Irritability
- Hunger
- Fast heartbeat
- Sweating
- Feeling jittery

The most common side effects of ZYTIGA include:1

- Feeling very tired
- Joint pain
- High blood pressure
- Nausea
- Swelling in your legs or feet
- Low blood potassium levels
- Hot flushes
- Diarrhea
- Vomiting
- Infected nose, sinuses, or throat (cold)
- Cough
- Headache
- Low red blood cells (anemia)
- High blood cholesterol and triglycerides
- High blood sugar levels
- Certain other abnormal blood tests

ZYTIGA 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.¹

These are not all the possible side effects of ZYTIGA. Call your healthcare provider for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.¹

ADDITIONAL INFORMATION

This information is provided ONLY in response to your request and is not intended as medical advice, to promote the use of our product, or suggest using it in any manner other than as described in the PRESCRIBING INFORMATION. All decisions regarding your medical treatment should be made with your healthcare professional(s). Please contact your healthcare professional(s) to discuss the information in this response.

Please refer to the attached full PRESCRIBING INFORMATION and the PATIENT INFORMATION for ZYTIGA.¹

REFERENCES

1. ZYTIGA (abiraterone acetate) [Prescribing Information]. Horhsam, PA: Janssen Biotech, Inc; https://www.janssenlabels.com/package-insert/product-monograph/prescribing-information/ZYTIGA-pi.pdf.