

Approved Use:

AZEDRA® (iobenguane I 131) is a prescription medicine used to treat adult and pediatric patients 12 years and older with cancers known as pheochromocytoma and paraganglioma that are positive for the norepinephrine transporter (as determined by an iobenguane scan), and who require systemic anticancer therapy.

Important Safety Information

AZEDRA can cause serious side effects. If you experience these side effects, your health care provider may need to adjust or stop your treatment. You should always follow your health care provider's instructions. Serious side effects may include:

Radiation exposure: Treatment with AZEDRA will expose you to radiation which can contribute to your overall long-term radiation exposure. Overall radiation exposure is associated with an increased risk for cancer. Radiation risk is greater in children than in adults. You should stay well hydrated before, during, and after your treatment and urinate frequently. Your doctor will advise you on how to lessen exposure to people who may come into contact with you after AZEDRA treatment.

Bone marrow problems and other cancers: Treatment with AZEDRA may cause your blood cell counts to drop (myelosuppression). Serious cases of myelosuppression have been observed during AZEDRA treatment. You may experience blood-related side effects such as low numbers of cells that are responsible for blood clotting (thrombocytopenia), low numbers of a type of white blood cells (neutropenia), and low red blood cells (anemia). Among the 88 patients who received a therapeutic dose of AZEDRA, 33% experienced Grade 4 thrombocytopenia, 16% experienced Grade 4 neutropenia, and 7% experienced Grade 4 anemia. Five percent of patients experienced febrile neutropenia (neutropenia with fever). People with low blood counts can develop serious infections. Your health care provider will routinely check your blood counts and tell you if they are too low. Tell your doctor if you experience any symptoms of low blood counts or infection, such as fever, chills, dizziness, shortness of breath, or increased bleeding or bruising. Your health care provider may need to adjust or stop your treatment accordingly. Other conditions that you may develop as a direct result of treatment with AZEDRA are blood and bone marrow cancers known as secondary myelodysplastic syndrome (MDS) and leukemia. MDS or acute leukemias were reported in 6.8% of the 88 patients who received a therapeutic dose of AZEDRA. The time to development of MDS or acute leukemia ranged from 12 months to 7 years. Two of the 88 patients developed other types of cancer.

Thyroid problems: Treatment with AZEDRA may increase your long-term risk of developing an underactive thyroid (hypothyroidism) or thyroid cancer. Hypothyroidism was reported in 3.4% of the 88 patients who received a therapeutic dose of AZEDRA. Take all thyroid-blocking agents as prescribed by your doctor to reduce the risk of these problems. You may need life-long monitoring for signs and symptoms of hypothyroidism.

Elevations in blood pressure: During or 24 hours following AZEDRA treatment, you may experience increases of blood pressure (hypertension) as a result of hormones released from your cancer. Eleven percent of the 88 patients who received a therapeutic dose of AZEDRA

experienced a worsening of pre-existing hypertension. All changes in blood pressure occurred within the first 24 hours after treatment. Monitor blood pressure frequently during the first 24 hours after each therapeutic dose of AZEDRA. Tell your doctor if you experience any cardiac-related symptoms.

Kidney problems: Treatment with AZEDRA will expose your kidneys to radiation and may impair their ability to work as normal. In some cases, patients have experienced kidney failure after treatment with AZEDRA. Of the 88 patients who received a therapeutic dose of AZEDRA, 7% developed kidney failure or acute kidney injury, and 22% experienced a decrease in kidney function measured at 6 or 12 months. Your health care provider will monitor your kidneys after treatment using blood tests, particularly if you already have kidney impairment before treatment.

Respiratory problems: Treatment with AZEDRA may cause noninfectious lung inflammation (pneumonitis). Tell your doctor if you experience shortness of breath, difficulty breathing, or cough.

Pregnancy warning: Before treatment with AZEDRA, tell your doctor if you are pregnant or plan to become pregnant. Exposure to radiation from treatment with AZEDRA can harm your unborn baby. Use an effective method of birth control during treatment with AZEDRA and for 7 months (for females) and 4 months (for males) after your final dose. Do not breastfeed during treatment with AZEDRA and for 80 days after your final dose.

Fertility problems: Treatment with AZEDRA may cause infertility due to radiation absorbed by your testes or ovaries over the treatment period that is within the range of exposure where temporary or permanent infertility may be expected.

The most common and most serious side effects of AZEDRA include decreased blood cell counts, nausea, vomiting and fatigue. These are not all the possible side effects of AZEDRA. For more information, ask your health care provider.

Drugs that reduce catecholamine uptake or that deplete catecholamine stores may interact with AZEDRA and may affect how well it works. These drugs were not permitted in the clinical trials. Tell your doctor before starting any medication, including over the counter medications, herbal or dietary supplements.

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch or call 1-800-FDA-1088.

Please see full Prescribing Information for AZEDRA.

Distributed by: Progenics Pharmaceuticals, Inc., NY 10007

Reference:

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