Patient Schedule for the AZEDRA® (iobenguane I 131) Therapeutic Regimen

AZEDRA® iobenguane I 131 injection for intravenous use

Patient Name: Referring Specialist:

DOSIMETRIC STEP

Start Thyroid Protection Medication*	**Visit 1†**		**Visit 2†**	**Visit 3†**	**Last Dose of Thyroid Protection Medication***
Date of First Dose: / /	**Dosimetric Dose** Day 0	**Gamma Camera Scan #1** Day 0	**Gamma Camera Scan #2** Day 1 or 2	**Gamma Camera Scan #3** Day 2, 3, 4, or 5	Date of Last Dose: / /
Medication: ☐ SSKI ☐ Lugol's Solution ☐ Potassium Iodide Tablet	Date/Time: /	Date/Time: /	Date/Time: /	Date/Time: /	Dosage:
Dosage:	Location:	Location:	Location:	Location:	
	Physician:	Physician:	Physician:	Physician:	
	Phone:	Phone:	Phone:	Phone:	

*To be completed by referring specialist. †To be completed by nuclear medicine department/facility.

IMPORTANT: Remember to take your thyroid protection medication.

Beginning 24 hours before Visit 1, be sure to take your thyroid protection medication. Otherwise, you cannot begin treatment with the AZEDRA therapeutic regimen. This medication is intended to minimize the harmful effects of radiation to your thyroid gland. You must continue taking this medication until 10 days after each AZEDRA dose. See Last Dose of Thyroid Protection Medication in the chart above.

To help you remember, fill in the boxes below with the dates your thyroid protection medication needs to be taken. Your doctor will tell you how many times a day you will need to take your medication. Every day you take it, check the box(es) for that day. (Check 1 box for once-a-day dosing, or check 3 boxes for 3-times-a-day dosing.)

Date: /	/	/	/	/	/	/	/	/	/
Dose: ☐ ☐ ☐	☐ ☐ ☐	☐ ☐ ☐	☐ ☐ ☐	☐ ☐ ☐	☐ ☐ ☐	☐ ☐ ☐	☐ ☐ ☐	☐ ☐ ☐	☐ ☐ ☐

REFERRING SPECIALIST OFFICE CONTACT INFORMATION	Referring Specialist:
	Nurse:
	Office Name:
	Address:
	Phone:
NUCLEAR MEDICINE CONTACT INFORMATION	Contact:
	Contact:
	Office Name:
	Address:
	Phone:

Patient Schedule for the AZEDRA® (iobenguane I 131) Therapeutic Regimen (cont.)

AZEDRA® iobenguane I 131 injection for intravenous use

THERAPEUTIC STEP

Start Thyroid Protection Medication*	Visit 4†		Last Dose of Thyroid Protection Medication*
Date of First Dose: / /	**Therapeutic Dose #1** Date/Time: /	Location:	Date of Last Dose: / /
Medication: ☐ SSKI ☐ Lugol's Solution ☐ Potassium Iodide Tablet	Physician:	Phone:	
Dosage:			Dosage:

*To be completed by referring specialist. †To be completed by nuclear medicine department/facility.

IMPORTANT: Remember to take your thyroid protection medication.

Beginning 24 hours before Therapeutic Dose 1, be sure to take your thyroid protection medication. Continue taking it until 10 days after each AZEDRA dose. See Last Dose of Thyroid Protection Medication above. Otherwise, you cannot begin treatment with the AZEDRA therapeutic regimen. This medication is intended to minimize the harmful effects of radiation to your thyroid gland.

To help you remember, fill in the boxes below with the dates your thyroid protection medication needs to be taken. Your doctor will tell you how many times a day you will need to take your medication. Every day you take it, check the box(es) for that day. (Check 1 box for once-a-day dosing, or check 3 boxes for 3-times-a-day dosing.)

Date: /	/	/	/	/	/	/	/	/	/
Dose: ☐☐☐	☐☐☐	☐☐☐	☐☐☐	☐☐☐	☐☐☐	☐☐☐	☐☐☐	☐☐☐	☐☐☐

THERAPEUTIC STEP

Start Thyroid Protection Medication*	Visit 5†		Last Dose of Thyroid Protection Medication*
Date of First Dose: / /	**Therapeutic Dose #2** Date/Time: /	Location:	Date of Last Dose: / /
Medication: ☐ SSKI ☐ Lugol's Solution ☐ Potassium Iodide Tablet	Physician:	Phone:	
Dosage:			Dosage:

*To be completed by referring specialist. †To be completed by nuclear medicine department/facility.

IMPORTANT: Remember to take your thyroid protection medication.

Beginning 24 hours before Therapeutic Dose 2, be sure to take your thyroid protection medication. Continue taking it until 10 days after each AZEDRA dose. See Last Dose of Thyroid Protection Medication above. Otherwise, you cannot begin treatment with the AZEDRA therapeutic regimen. This medication is intended to minimize the harmful effects of radiation to your thyroid gland.

To help you remember, fill in the boxes below with the dates your thyroid protection medication needs to be taken. Your doctor will tell you how many times a day you will need to take your medication. Every day you take it, check the box(es) for that day. (Check 1 box for once-a-day dosing, or check 3 boxes for 3-times-a-day dosing.)

Date: /	/	/	/	/	/	/	/	/	/
Dose: ☐☐☐	☐☐☐	☐☐☐	☐☐☐	☐☐☐	☐☐☐	☐☐☐	☐☐☐	☐☐☐	☐☐☐

Please see Important Safety Information on page 4 and click here for full Prescribing Information.

Instructions to the Released Patient

AZEDRA® (iobenguane I 131) emits gamma radiation in addition to beta radiation. Gamma radiation can escape from the body, therefore special radiation precautions must be taken for about _____ weeks after AZEDRA therapy.

Patient Identifier: Administration Date: / /

Activity administered (A): mCi: Measured dose rate: mrem/h at 1 meter

For you to be discharged from the hospital, you must follow these precautionary measures:

INSTRUCTION	DURATION (DAYS)
1. Continue thyroid protection medication as instructed	
2. Sleep in a separate bed (at least 6 feet separation)	
3. Do not take a long trip (4 hours or more) sitting near others (e.g., car, train, airplane, bus)	

4. Other instructions:

In addition, while following the above instructions, you must:

- Maintain a distance of at least 6 feet from others whenever possible
- Avoid contact with pregnant women and children
- When taking shorter trips during the period of restricted travel, sit as far as possible from others
- Hold clothing and linen (sheets and towels) for 1 week before washing and wash separately from rest of household
- Use separate wash cloths, towels, and toothbrushes from rest of household
- Have sole use of the bathroom, if possible
- Wash hands frequently, especially after using the toilet
- Shower daily
- Sit while urinating and flush the toilet twice with the lid down
- Use separate dishes and utensils for 1 week and wash separately
- Avoid sharing any bodily fluids (avoid kissing, for example)
- Use a condom for sex
- Avoid using disposable items that cannot be flushed down the toilet (women should use flushable tampons)
- Drink plenty of liquids
- Show these instructions to any physician or other healthcare provider visited

SIGNATURES	DATE
Physician:	/ /
Radiation Safety Officer:	/ /
Patient/Guardian:	/ /

Important Safety Information for Patients

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: Trreatment 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 click here for full Prescribing Information for AZEDRA.

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