# Product Indications and Important Safety Information – AdreView

## PRODUCT INDICATIONS AND USE

AdreView™ (Iobenguane I 123 Injection) is a radiopharmaceutical indicated for: (1) Use in the detection of primary or metastatic pheochromocytoma or neuroblastoma as an adjunct to other diagnostic tests and (2) Scintigraphic imaging assessment of sympathetic innervation of the myocardium to assist in the evaluation of adult patients with NYHA Class II or Class III heart failure and left ventricular ejection fraction ≤35% to help identify patients with lower one- and two-year mortality risks, as indicated by a heart-to-mediastinum (H/M) ratio of radioactivity uptake ≥1.6.

**Limitations**: In patients with congestive heart failure (CHF), AdreView utility has not been established for selecting therapy, monitoring response to therapy, or identifying a patient with a high risk of death.

**Important Safety Information About AdreView™ (Iobenguane I 123 Injection)**

## CONTRAINDICATIONS

- AdreView is contraindicated in patients with known hypersensitivity to iobenguane or iobenguane sulfate

## WARNINGS AND PRECAUTIONS

- **Hypersensitivity Reactions:** Hypersensitivity reactions have followed AdreView administration. Have anaphylactic and hypersensitivity treatment measures available prior to administration
- **Medication Withdrawal:** Drugs that inhibit norepinephrine uptake, deplete norepinephrine stores, inhibit norepinephrine transporter function and sympathetic amines may decrease uptake of AdreView and impact the risk for unreliable imaging results. When medically feasible, withdraw these drugs before AdreView administration and monitor patients for clinically significant withdrawal symptoms
- **Risk of Serious Reactions in Infants due to Benzyl Alcohol Preservative:** Serious and fatal adverse reactions including "gasping syndrome" (characterized by central nervous system depression, metabolic acidosis, and gasping respirations) can occur in neonates and infants treated with benzyl alcohol-preserved drugs, including AdreView
- **Increased Radiation Exposure in Patients with Severe Renal Impairment:** As AdreView is cleared by glomerular filtration and is not dialyzable, these patients may have increased radiation exposure, impact H/M ratios and decrease image quality. Safety and efficacy have not been established in these patients
- **Imaging Errors due to Conditions that Affect the Sympathetic Nervous System:** Imaging in individuals with these conditions may show decreased cardiac uptake independent of heart disease
- **Thyroid Accumulation:** Administer thyroid blockade to patients at risk of iodine 123 accumulation in the thyroid
- **Hypertension:** AdreView may increase release of norepinephrine from chromaffin granules producing transient hypertension

## ADVERSE REACTIONS

- Adverse reactions, including hypersensitivity reactions, have been reported following AdreView administration
- The most common adverse reactions in NDA clinical trials — dizziness, rash, pruritus, flushing, headache, and injection-site reactions — occurred in ≤1.3% of patients

**USE IN SPECIFIC POPULATIONS**

- **Pregnancy:** Radioactive iodine products cross the placenta and can permanently impair fetal thyroid function. Administration of a thyroid blocking agent is recommended before use of AdreView use in pregnant women. All radiopharmaceuticals have potential to cause fetal harm. There are no available data on AdreView in pregnant woman to evaluate drug associated risk of major birth defects, miscarriage or adverse maternal or fetal outcome. Advise pregnant women of the potential risks of fetal exposure to radiation with administration of AdreView
- **Lactation:** Iodine 123, the radionuclide in AdreView, is present in human milk. There is no information on the effects on breastfed infants or on milk. Advise a lactating woman to interrupt breast feeding and pump and discard breast milk for at least six days after AdreView administration to minimize radiation exposure to breastfeeding infant
- **Pediatric Use:** Safety and effectiveness have not been established in pediatric patients <1 month of age or in any pediatric patients with congestive heart failure (CHF). When administering AdreView in infants consider the combined daily metabolic load of benzyl alcohol from all sources including AdreView (contains 10.3 mg of benzyl alcohol per mL) and other drugs containing benzyl alcohol. The minimum amount of benzyl alcohol at which serious adverse reactions may occur is not known
- **Geriatric Use:** Clinical experience has not identified differences in responses between the elderly and younger patients. Because elderly patients are more likely to have decreased renal function, care should be taken in dose selection and image interpretation. Consider assessment of renal function in elderly patients prior to AdreView administration

**OVERDOSAGE**

- Iobenguane is not cleared by dialysis. The major risks of overdosage relate to increased radiation exposure and long-term risk for neoplasia. In case of radioactivity overdosage, frequent urination should be encouraged to minimize radiation exposure to the patient

**Prior to AdreView administration, please read the full Prescribing Information for additional Important Safety Information.**

**To report SUSPECTED ADVERSE REACTIONS, contact GE Healthcare at 800 654 0118 (option 2, then option 1) or the FDA at 800 FDA 1088 or www.fda.gov/medwatch.**