

## NATIONAL PBM COMMUNICATION · November 15, 2011

---

### **Lexiscan® (Regadenoson) Update: New Safety Labeling Changes Approved By FDA**

- Additional labeling revisions for Regadenoson (Lexiscan®) as of September 2011 now include:
  - Updated WARNINGS AND PRECAUTIONS that address -
    - **Hypersensitivity, including anaphylaxis**
      - Reported in < 1% of patients.
      - Symptoms = anaphylaxis, angioedema, cardiac or respiratory distress, decreased oxygen saturation, hypotension, throat tightness, urticaria, and rashes.
    - **Bronchoconstriction**
      - A randomized, controlled trial of nearly 1000 patients (about half diagnosed with asthma and half with chronic obstructive pulmonary disease) revealed more reports of dyspnea/wheezing with Regadenoson (Lexiscan®) than placebo, but no significant reduction in FEV1.
      - Most resolved without therapy, but few required medical intervention with aminophylline or short-acting bronchodilators.
  - New study data regarding –
    - **Drug interactions with caffeine** (200mg or 400mg), which may reduce the detection of reversible ischemic defects by as much as 60%. Existing recommendations to avoid consumption of any methylxanthines 12 hours prior to Regadenoson (Lexiscan®) remain unchanged.
    - **Renal impairment**, and results that showed no serious adverse events reported in patients with NKFK/DOQI Stage III or IV (defined as GFR 15-59 ml/min/1.73m<sup>2</sup>) 24 hours after Regadenoson (Lexiscan®) administration.
- Updated labeling can be accessed at: [http://www.accessdata.fda.gov/drugsatfda\\_docs/label/2011/022161s009lbl.pdf](http://www.accessdata.fda.gov/drugsatfda_docs/label/2011/022161s009lbl.pdf) .
- Previous PBM Communications in May 2009 and September 2010 addressed prior labeling changes of adverse events observed post-marketing, such as unexpected GI/musculoskeletal effects as well as marked hypertension, tremor, and seizure.
- Within the VA system, a total of 41 reports of adverse drug events associated with regadenoson have been submitted to the VA Adverse Drug Event Reporting System (VA ADERS) between June 2009 through mid-October 2011.
  - 9/41 were classified as severe. Reactions included hypotension, cardiac arrest, palpitations, tachycardia, bradycardia, convulsion, dyspnea, respiratory distress, respiratory depression, throat tightness, and bronchospasm.
  - 20/41 were classified as moderate.
  - Providers should continue to report any adverse events with regadenoson by entering the information into CPRS' Allergies/Adverse Reactions field and/or via local reporting mechanisms. Facilities should continue to report adverse events into VA ADERS and to the FDA (as appropriate).

#### **REFERENCES:**

1. Lexiscan® (regadenoson) injection [package insert]. Deerfield, IL: Astellas Pharma US, Inc.; September 2011.
2. Lexiscan® (regadenoson) injection Detailed View: Safety Labeling Changes Approved By FDA Center for Drug Evaluation and Research (CDER). <http://www.fda.gov/Safety/MedWatch/SafetyInformation/ucm197103.htm> . Accessed 10/21/2011.

#### **ACTIONS**

- **Facility Director** (or physician designee): Forward this document to the Facility Chief of Staff (COS).
- **Facility COS and Chief Nurse Executives:** Forward this document to all appropriate providers who prescribe these medications (e.g., cardiologists and nuclear medicine clinicians as well as nurses and technicians who work in imaging settings, including contract providers, etc.). In addition, forward to the Associate Chief of Staff (ACOS) for Research and Development (R&D). Forward to other VA employees as deemed appropriate.
- **ACOS for R&D:** Forward this document to Principal Investigators (PIs) who have authority to practice at the facility and to your respective Institutional Review Board (IRB).