

NATIONAL PBM COMMUNICATION · March 4, 2013

Peginesatide (Omontys®) Injection Recall Due to Serious Hypersensitivity Reactions

- On February 23, 2013, Takeda Pharmaceutical Company Limited (Takeda) initiated a recall of all lots of peginesatide (OMONTYS®) injection to the user level due to new post-marketing reports of serious hypersensitivity reactions, including life-threatening anaphylaxis.
- Peginesatide (OMONTYS®) was approved in March 2012 for the treatment of anemia due to chronic kidney disease in adult patients on dialysis. In November 2012, the manufacturer of peginesatide (OMONTYS®) updated their product information to include a contraindication in patients with serious allergic reactions to peginesatide (OMONTYS®). Under Warnings and Precautions, it was added that serious allergic reactions, including anaphylactic reactions, hypotension, bronchospasm, angioedema and generalized pruritus may occur; and that peginesatide (OMONTYS®) should be immediately and permanently discontinued and appropriate therapy administered if a serious allergic reaction were to occur.
- Peginesatide (OMONTYS®) is indicated for the treatment of anemia due to chronic kidney disease in adult patients on dialysis. Peginesatide (OMONTYS®) is not approved for use in patients with anemia due to chronic kidney disease who are not on dialysis or in patients receiving treatment for cancer who have anemia that is not due to chronic kidney disease.
 - Hypersensitivity reactions associated with peginesatide (OMONTYS®) injection occur at an approximate rate of 0.2%, out of which a third of these are serious (i.e., anaphylaxis requiring prompt medical intervention and/or hospitalization).
 - Serious hypersensitivity reactions have occurred within 30 minutes after such administration of peginesatide (OMONTYS®), with approximately 0.02% of patients experiencing fatal reactions following the first dose of intravenous administration.
 - There are no reports of such reactions following subsequent dosing, or in patients who have completed their dialysis session.

PRODUCT SEQUESTERING ACTIONS

- Details of affected lot (s) include:

PEGINESATIDE (OMONTYS®)	NDC	LOT NUMBER
10MG MULTI-DOSE VIALS	64764-610-10	C18685, C18881, C19258
20MG MULTI-DOSE VIAS	64764-620-20	C18686, C18696

- Following the action due dates in **Product Recall Office Log # 3458** (available at: <http://vaww.recalls.ncps.med.va.gov/WebRecalls/Recalls.html>), sequester and then return all remaining affected product at the CMOP/facility per manufacturer's instructions. Please inform your FRC when completed.
- Providers should continue to report any adverse reactions with the use of peginesatide (OMONTYS®) by entering the information into CPRS' Allergies/ Adverse Reactions field and/or via local reporting mechanisms. Adverse events should also be reported, as appropriate, to the VA ADERS program and FDA MedWatch (1-800-FDA-1088, fax 1-800-FDA-0178, online at <https://www.accessdata.fda.gov/scripts/medwatch/medwatch-online.htm>, or by mail).

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 this agent (e.g., **primary care providers, nephrologists, and pharmacy staff, 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).