# *NATIONAL PBM COMMUNICATION · April 2, 2009*

## *Watson Pharmaceuticals Initiated an Urgent Drug Recall of Infed (Iron Dextran) Inj 50mg/mL Due to Potential for Precipitate Formation*

- On March 16, 2009, Watson Pharmaceuticals issued an Urgent Drug Recall for INFeD (Iron Dextran) 50mg/mL due to the possibility of precipitate formation in the injection solution.
- This is a RETAIL level recall.
- Particulate matter in the injection solution becomes a risk if administered intravenously.
- The following lot numbers are being recalled:

| Product Code | Product Description | NDC | Lot Number's |
|---|---|---|---|
| 430-1228 | Infed (Iron Dextran) Inj 50mg/mL 10/bx | 52544093102 | 06K110A, 06L010A, 06L030B, 06L050A, 06L060A, 06L110A, 06L120B, 06L140A, 06M140A |

- Return all remaining product at the facility/CMOP level with the affected lot number to McKesson, NOT as instructed in the product recall documents. Please inform your Facility Recall Coordinator when completed.
- Determine whether the affected lot numbers (refer to lot numbers provided above) were dispensed to any patient(s) for home administration.
- If an affected lot was dispensed to a patient(s) for home administration, then:
  - Identify the patient(s).
  - Contact patient(s) who may have received the affected product for home administration by any appropriate method.
    - A sample letter can be found at: http://vaww.national.cmop.va.gov/PBM/Other%20Documents%20and%20Resources/Recall%20Patient%20Letter%20Template.doc.
    - This template can be altered according to site-specific needs.
  - Provide patient(s) with instructions on the following:
    - How to obtain a new supply of medication.
    - How to return the medication being recalled to the pharmacy.
    - To continue taking the medication with the affected lot number until they receive a new supply of iron dextran. When correct medication is received, patient should begin taking the new medication and return the recalled supply as instructed.
- Report any adverse reactions experienced with the use of this medication to the VA ADERS program.
- Refer to https://www.oncologysupply.com/content/oncsupply/cms/files/Watson167V_Infed_Recall.pdf for further details regarding this urgent drug recall.

*ACTIONS:*

- ***Facility Director*** *(or physician designee): Report completion of actions to the VISN Director.*
- ***Facility COS:*** *Forward this document to all appropriate providers who prescribe this agent (e.g.,* ***primary care providers, heme-onc providers, and renal specialists,*** *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. Report completion of actions to the Facility Director.*
- ***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).*
- ***VISN Directors:*** *Within 10 business days of receipt (due 04/16/2009), communicate to PBM/VAMedSAFE that all actions have been completed via the Feedback tool: http://vaww.national.cmop.va.gov/PBM/visn_drug_recalls_alerts/default.aspx.*