

NATIONAL PBM RESPONSE TO ORTHO BIOTECH ANNOUNCING NATIONWIDE VOLUNTARY RECALL OF PROCRI[®]T (EPOETIN ALFA) LOT NUMBER P114942A August 8, 2008

Ortho Biotech is announcing that it is voluntarily recalling one lot (P114942A) of PROCRI[®]T (Epoetin alfa) after having identified cracks in the necks of a small number of vials upon post-manufacturing inspection. No other lot of this product is affected by this recall.

PROCRI[®]T (Epoetin alfa) is used in the management of patients with anemia. The following PROCRI[®]T (Epoetin alfa) products carry the affected lot number:

NDC	Description	Lot Number	Expiration Date
59676-312-00	Individual multi-dose vials of PROCRI [®] T (Epoetin alfa) 10,000 U/2mL	P114942A	12/10
59676-312-04	Cartons containing 4 multi-dose vials of PROCRI [®] T (Epoetin alfa) 10,000 U/2mL	P114942A	12/10

Approximately 44,292 vials of lot P114942A in the above packaging configurations were distributed between April 15, 2008 and July 17, 2008. Vials exhibiting even slight cracks may not maintain their sterile condition and should not be used for subcutaneous or intravenous injection.

VA MEDSAFE RECOMMENDATIONS *reinforce those of the manufacturer and include:*

- Determine whether the affected lot numbers of PROCRI[®]T (Epoetin alfa) (NDC numbers 59676-312-00 and 59676-312-04 ; Lot P114942A; Expiration December 2010) were dispensed to the patient and if so, identify the patients who may have received the affected product and determine the most appropriate method of notifying the patient (a phone call is the first choice; if unable to reach by phone, use/modify accompanying patient letter) with instructions on how to return the affected product and receive a new prescription.
- Patients should be advised to contact their Healthcare Provider if they have received and are in possession of PROCRI[®]T (Epoetin alfa) (NDC numbers 59676-312-00 and 59676-312-04; Lot P114942A; Expiration December 2010).
- Check all floor stock and all remaining product with the affected lot number at the facility/CMOP level should be returned to McKesson, NOT as instructed in the Ortho Biotech Press Release (see link below).
- Within 5 business days, the Chiefs of Pharmacy are requested to report and confirm to their VISN Formulary Leader or designee that all appropriate patients have been notified, the method notified (e.g. phone call, letter) and date each method was completed.

- **VISN Formulary Leaders (or designee) will then report back this information to the National PBM via the Feedback tool:**
http://vaww.national.cmop.va.gov/PBM/visn_drug_recalls_alerts/Lists/Procrit%20Epoetin%20alfa/overview.aspx. PBM will summarize results and forward to 10N (DUSHOM).
- **CMOP and EPS should also respond to the Feedback Tool above for their specific questions.**
- **Further information regarding the affected lots of PROCRI[®] (Epoetin alfa) can be accessed via the following link:**
<http://www.orthobiotech.com/orthobiotech/assets/recall.pr.notice.pdf>.