



## URGENT: Component Pack Field Correction

November 20, 2008

Subject: Field Correction for Component Pack packaged with Mononine<sup>®</sup>,  
(Coagulation Factor IX, Human)

Dear Customer:

CSL Behring L.L.C. is notifying you of an issue with respect to the components for infusion provided for use with five (5) specific lots of Mononine<sup>®</sup>.

We have identified an incidence of component packs that did not have a complete seal between the soft blister pack and the package cover. As a precaution, we are issuing this letter to you as our records indicated you have been shipped one or more of the affected lots listed below. This field correction is being done with the knowledge of the U.S. Food and Drug Administration.

Mononine <sup>®</sup> Lot Number	NDC Number	Component Pack Lot Number	Mononine <sup>®</sup> Expiration Date
J22306	0053-7668-04	60970417	06/19/2010
J22506	0053-7668-04	60970417	06/29/2010
J22607	0053-7668-04	60970417	07/09/2010
J22707	0053-7668-04	60970417	07/14/2010
J23208	0053-7668-04	60970417	08/15/2010

**NOTE: Mononine<sup>®</sup> vials are not affected, only the component packs.  
DO NOT RETURN ANY MONONINE<sup>®</sup> VIALS.**

CSL Behring will be shipping sufficient replacement component packs to direct customers.

Please immediately take the following actions:

1. To determine if your inventory is effected, please match both the product lot number and the component pack lot number in the provided list above. The combination of the two lot numbers must match to be effected by this field correction.

## CSL Behring

2. This field correction is to the pharmacy level. Please forward this letter along with replacement component packs to any pharmacies, hospitals, clinics, etc that you service.
3. If you are administering Mononine<sup>®</sup>, please use the replacement component pack and discard the original component pack provided with the product.
4. If you are not a CSL Behring direct customer, please tell your distributor the quantity of inventory on hand and ask that they send replacement component packs for your inventory.
5. Complete and fax back the enclosed form indicating the number of units from these lots of Mononine<sup>®</sup> in your inventory and confirm that the component packs have been replaced with component packs provided with this letter.
6. Discard the original component pack.

Please be advised this is not a field correction of Mononine<sup>®</sup>. This is only a field correction of the component pack that was packaged with specific lot numbers of Mononine<sup>®</sup>. It is important to note that there is no problem with Mononine<sup>®</sup> product or diluent.

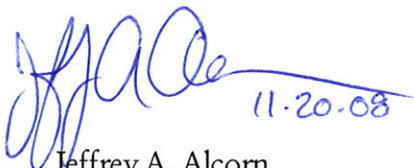
Please note that since the product is not involved in this field correction, CSL Behring will continue to ship these lot numbers of Mononine<sup>®</sup> with replacement component packs.

Customer Support: 1(800) 683-1288 For questions concerning component packs.  
Medical Information: 1(800) 504-5434 For Medical Information queries.

In the event of an emergency, physician should contact Medical Affairs (Dr. Garrett Bergman 640-620-4350, or Dr. James Cappola 484-682-7106).

Thank you for your cooperation in this matter.

Sincerely,



Jeffrey A. Alcorn  
Sr. Director, Quality  
CSL Behring L.L.C.

**CSL BEHRING L.L.C.**  
**Attn: Customer Support**  
**1020 First Avenue**  
**King of Prussia, PA 19406**

**Fax: 610-878-4888**

**Telephone: 1-800-683-1288**

**URGENT Component Pack Field Correction**  
**For component packs associated with Mononine lots:**

Mononine® Lot Number	NDC Number	Component Pack Lot Number	Mononine® Expiration Date
J22306	0053-7668-04	60970417	06/19/2010
J22506	0053-7668-04	60970417	06/29/2010
J22607	0053-7668-04	60970417	07/09/2010
J22707	0053-7668-04	60970417	07/14/2010
J23208	0053-7668-04	60970417	08/15/2010

**NOTE: Mononine® vials are not affected, only the component packs.**  
**DO NOT RETURN ANY MONONINE® VIALS.**

Please complete and fax this page back to the number above even if you do not have inventory.

No inventory in stock.

Inventory in stock of \_\_\_\_\_ vials. We have replaced the component packs.

Whether or not you have inventory, please complete this portion.

Institution \_\_\_\_\_

Address \_\_\_\_\_

City/State/Zip \_\_\_\_\_

Telephone Number \_\_\_\_\_

Print name \_\_\_\_\_

Signature / Date \_\_\_\_\_