

June 03, 2019

Urgent: CSL Behring L.L.C. Issues a Voluntary Recall of One Lot of Coagulation Factor IX (Human), Mononine®

Dear ASD Healthcare Customer:

CSL Behring L.L.C. is initiating a voluntary recall of one lot (batch) of Coagulation Factor IX (Human), Mononine. The affected batch information is listed below.

This batch is being voluntarily recalled as a precautionary measure due to the potential for inadequate aseptic technique during the filling process. CSL Behring L.L.C. is requesting that the use of this batch be immediately discontinued and the product be returned to the company.

CSL Behring L.L.C. provided the following affected lot information:

Product Description	Lot # / Batch	Expiration Date
Mononine	Y25709	Sep 13, 2020

To reduce any risk, we ask for your cooperation in taking the following action:

- **Please examine your inventory immediately to determine if you have any impacted product in stock.**
- **If you do have inventory of any of the recalled lot numbers**, please stop distribution and dispensing of the product and quarantine impacted units.
- **Use ASD Healthcare's online [Request a Return](#) tool to begin the return process.** A return label and further return directions will then be provided.
- Arrange for product to be returned to ASD Healthcare.

For the full recall notice, please view the attached document on the following pages.

If you have any questions or concerns, please contact ASD Healthcare's customer service at **800.746.6273**.

CSL Behring

May 31, 2019

URGENT: VOLUNTARY BIOLOGIC RECALL

Subject: Coagulation Factor IX, Human
Mononine®
Batch Numbers Y25709

Dear Colleague:

This is to inform you of a product recall involving:

CSL Behring L.L.C., Mononine® batch Y25709 with expiration date of 13Sept2020.

This batch is being voluntarily recalled as a precautionary measure due to the potential for inadequate aseptic technique during the filling process. CSL Behring L.L.C. is requesting that the use of this batch be immediately discontinued and the product be returned to the company.

Vials from Mononine® 25%, batch Y25709 were distributed to the market beginning 8Oct2018. Our records indicate that you have been shipped vials from Mononine® batch Y25709.

This recall is to the pharmacy level.

Please examine your inventory of Mononine® batch Y25709 and please immediately discontinue distribution and use of any on-hand stock from this batch. Return that stock to CSL Behring L.L.C.

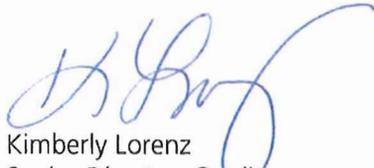
Regardless of whether or not you have any inventory or product from this batch, please immediately take the following actions:

- 1) If you have any inventory of Mononine®, batch Y25709, please complete a request to return product to your distributor and return all vials in inventory of Mononine®, batch Y25709, per their instructions.
- 2) If you have further distributed this batch, you should notify your customers to the pharmacy level. Your notification to your customers may be enhanced by including a copy of this recall notification letter.

PLEASE NOTE THAT RETURNS ARE LIMITED TO INVENTORY OF Mononine®, batch Y25709 ONLY.
THERE WILL BE NO CREDIT GIVEN FOR RETURNS OF ANY OTHER BATCHES OF Mononine THAT
YOU HAVE IN INVENTORY OR RETURNED BY YOUR CUSTOMERS.

Thank you for your cooperation in this matter.

Sincerely,

A handwritten signature in blue ink, appearing to read 'K. Lorenz', with a large, sweeping flourish extending to the right.

Kimberly Lorenz
Senior Director, Quality
CSL Behring LLC Kankakee