



Date: January 20, 2021

URGENT: VOLUNTARY PRODUCT RECALL

Subject: **Coagulation Factor IX (Human)
Mononine® 1000 IU
Batch Numbers: See chart below
NDC Number: 0053-6233-02**

Dear Customer:

This letter is to inform you of a product recall being initiated by CSL Behring.

As a precautionary measure, CSL Behring has instituted a Class II voluntary recall of MONONINE at the hospital /pharmacy level, due to a manufacturing deviation that occurred during the filling process.

Our commitment to patient care continues to be a key priority and guiding principle and our goal is to always manage supply so that patients experience minimal disruption.

We are currently assessing how this will impact the supply situation for MONONINE. As MONONINE production has been discontinued, we will not be resuming regular distribution and will have limited ability to provide additional product.

Due to this unforeseen constraint on supply, it is very important that all patients currently taking MONONINE speak with their Healthcare Professional to select a new product immediately.

The table below provides detail for all impacted batches of MONONINE that were shipped from CSL Behring beginning in April 2020:

Mononine® 1000 IU NDC: 0053-6233-02	
BATCH	EXPIRY DATE
P100125501	8/28/2021

The Food and Drug Administration has been notified of this recall.

Examine your current inventory and if you have an impacted batch, contact your Authorized Distributor’s Customer Service to facilitate a return to them.

