

URGENT: BIOLOGIC RECALL INFORMATION

Initiated by : CSL Behring

Event Id : 178

Event Date : 06-06-2019



Therapy	Mononine®				
	NDC Number	Lot Number	Size	Packaging	Expiration Date
	0053-6233-02	Y25709	1000 IU	-	09-13-2020
Reason	<p>CSL Behring is initiating a Voluntary Biological Product Recall as a precautionary measure for one lot of its Coagulation Factor IX (Human) Mononine®. NDC: 0053-6233-02</p> <p>This lot is being voluntarily recalled as a precautionary measure due to a manufacturing deviation. CSL Behring made the decision to institute a voluntary recall, at the pharmacy level, to address the potential for a deviation during the filling process.</p> <p>The recalled lot is Y25709 with an expiration date of 13 Sep 2020. Vials from this Mononine® lot were distributed to the market in October 2018.</p> <p>Only the one mentioned lot is subject to this notification; all other Mononine® lots on the market are unaffected and may continue to be used. As agreed with the U.S. Food and Drug Administration (FDA), this recall is going to the pharmacy level.</p>				
Action	<p>Pharmacies: Immediately quarantine inventory of the affected product under your direct control and contact your supplier to arrange for return of the identified product.</p> <p>Patients: Contact your pharmacy to arrange return of the recalled lot.</p>				
Other Information	<p>This product recall is being conducted with the knowledge of the Food and Drug Administration.</p> <p>For Medical Inquiries please contact CSL Behring Medical Information via phone at 1-800-504-5434 or via email at MedinfoNA@cslbehring.com.</p>				