

16-January-2020

URGENT: BIOLOGIC PRODUCT RECALL

Subject: Hizentra Pre-Filled Syringe
P100047093
CSL-RN01-01-2020

Dear Customer:

CSL Behring Canada Inc. has voluntarily decided to initiate a recall of one (1) lot of Hizentra. CSL Behring requests that all distribution of the impacted lot be stopped immediately. This action is being taken with the knowledge of the Health Canada Inspectorate Program.

The Recall classification is a Type II – and includes all products currently within the distribution network (including patients, Hospitals/Blood Banks and Canadian Blood Services depots).

The details of the lot being recalled are as follows:

Product	DIN	Lot Number	Expiry Date
Hizentra PFS 2g (10mL)	02463067	P100047093	06-AUG-2021

This lot of Hizentra is being recalled due to a number of Product Technical Complaints that have identified syringes with an atypical appearance (viscous or gelatinous solution). As a precaution CSL Behring requests that patients return all unopened syringes of lot P100047093 to the Hospital or Blood Bank where the product was dispensed.

The preliminary Medical Safety Assessment categorizes this to be a very low risk to patients as the incident is considered self-limiting due to the fact that the observed phenomenon is highly identifiable and it is considered difficult to administer the product if it exhibits the gelatinous appearance.

Further information regarding how to process the returned product will be provided to the Hospitals/Blood Banks by Canadian Blood Services.

CSL Behring is requesting immediate action. A response within 5 days is appreciated.

Thank-you for your attention in this matter.

Sincerely,



Rob Bukovcan
Senior Manager Quality Assurance/Compliance, Canada
CSL Behring Canada Inc.