

CSL Behring

Biotherapies for Life™

CSL Behring
1020 First Avenue
PO Box 61501
King of Prussia, PA 19406-0901

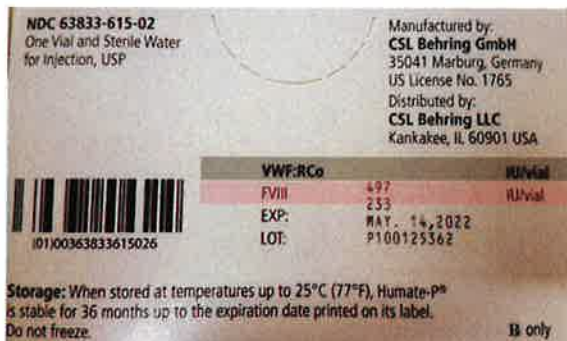
IMPORTANT DRUG INFORMATION

October 3, 2019

Dear Customer,

The purpose of this letter is to alert you about a misalignment in the printing of the data on the **folding box of Humate-P®** [Antihemophilic Factor/von Willebrand Factor Complex (Human)] that might lead to confusion of the user. This concerns lots of all fill sizes (600, 1200, 2400 IUs) distributed by CSL Behring since February 2019.

On the **folding box of Humate-P®** the data for von Willebrand Factor Ristocetin Cofactor and Factor VIII potency, as well as expiry date and lot number are imprinted next to the preprinted text fields stating **"VWF:RCo", "FVIII", "EXP" and "LOT"**. Due to an error during packaging, the potency data was shifted downwards. (See Pictures Below).



Representative sample of an **affected** lot



Representative sample of a **non-affected** lot

Although positioned incorrectly, the printed potency values on the folding box are correct.

Due to the **incorrect positioning**, the actual von Willebrand Factor (VWF:RCo) data could be mistaken as FVIII potency (FVIII) data.

As the data on all Humate-P® vial labels are positioned correctly and cannot be misinterpreted, we kindly ask that all users refer to the vial label for dosage calculations and follow instructions for use in the Prescribing Information

Please contact our Medical Information team directly if you have any questions.

PTC Reporting Contact information:

Telephone: 800-504-5434

EMAIL: MedinfoNA@cslbehring.com

Humate-P® will continue to be available. We would like to assure you that supplying the market reliably is a priority for CSL Behring. We thank you for your understanding and continued trust.

Sincerely,



Debra Bensen-Kennedy

Vice President North America Medical Affairs

CSL Behring, LLC