



Grifols – Recall of Profilnine[®], Factor IX Complex

- On June 15, 2018 Grifols announced a patient-level recall of one lot of [Profilnine, Factor IX Complex](#) because the incorrect volume of sterile water for injection was packaged with Profilnine.
- Recalled lot of Profilnine:

Product Description	NDC #	Lot # (expiration date)
Profilnine, Factor IX Complex, 1000 units	68516-3208-2	A1PBB00072 (1/31/2020)

- Profilnine, Factor IX Complex, is indicated for the prevention and control of bleeding in patients with factor IX deficiency (hemophilia B). Profilnine contains non-therapeutic levels of factor VII and is not indicated for use in the treatment of factor VII deficiency.
- Per Grifols, reconstituting the recalled product with the incorrect volume of sterile water for injection may cause an injection site reaction. This recall is being conducted as a precautionary measure and is considered low risk to the patient.
 - This notice pertains only to the volume of sterile water for injection packaged with this lot.
 - Based on the current data available, the manufacturer concludes that there are no serious safety issues identified with the recalled lot.
- Patients should contact their physician or healthcare provider if they have experienced any problems that may be related to taking or using the recalled product.
- Patients that are currently using the recalled lot of Profilnine should contact their healthcare provider or hemophilia treatment center to learn about other available treatment options.
- Physicians should distribute information regarding the Profilnine recall to all providers in their respective area that treat patients with hemophilia.
- For more information regarding this recall, contact Grifols at **1-888-474-3657**.



OptumRx[®] specializes in the delivery, clinical management and affordability of prescription medications and consumer health products. We are an Optum[®] company — a leading provider of integrated health services. Learn more at optum.com.

All Optum[®] trademarks and logos are owned by Optum, Inc. All other brand or product names are trademarks or registered marks of their respective owners.

This document contains information that is considered proprietary to OptumRx and should not be reproduced without the express written consent of OptumRx.

RxNews[®] is published by the OptumRx Clinical Services Department.

©2018 Optum, Inc. All rights reserved.