

July 9, 2019

Fresenius Kabi Responds to a Potential Shortage of Heparin Sodium

To our U.S. customers,

We've been working closely with the U.S. Food and Drug Administration, ASHP Drug Shortage and our raw material suppliers to help respond to, and mitigate, a potential shortage of Heparin Sodium in the United States. The potential shortage stems from supply interruptions at other finished-dose manufacturers as well as an outbreak of swine fever in China, which is a major global supplier of the active pharmaceutical ingredient (API) in Heparin (Heparin is derived from porcine intestinal mucosa).

At Fresenius Kabi, we do not rely solely on China for API. We source from multiple suppliers and geographies to serve our customers, but the situation in China is expected to cause API supply constraints globally for an unknown period.

As mentioned above, the market is also experiencing finished product supply interruptions from other manufacturers. This has significantly increased demand for Fresenius Kabi Heparin. As a leader in injectable medications and a leading supplier of Heparin, Fresenius Kabi has put plans in place to monitor the market and to help mitigate a potential future Heparin shortage.

We understand the significance of Heparin to patient care and are committed to solutions that support you and your patients. We have met increased demand to date, and to maintain long-term supply continuity, we have begun limiting shipments of our Heparin presentations based on historical demand. Please see **Tables 1-4** below for a full list of our current Heparin product offerings.

We will continue to work closely with our customers, suppliers, ASHP Drug Shortage and the FDA to assess and respond appropriately to evolving market dynamics.

For clinical questions, please contact Fresenius Kabi USA Medical Affairs at 1-800-551-7176, Monday-Friday between 8 a.m. and 5 p.m. (CST) or email medinfo.USA@fresenius-kabi.com. For product-availability updates, please visit our web site at www.fresenius-kabi.com/us/pharmaceutical-product-availability, or call our Customer Service team at 1-888-386-1300.

For updates on global Heparin supply, please see FDA's web site at <https://www.fda.gov/drugs/drug-safety-and-availability/drug-shortages>.

Sincerely,



Dennis Preusker

Senior Director, Marketing

Table 1

Heparin Sodium Injection Vials	
NDC	Description
63323054001	Heparin Sodium 1,000USP 1mL MDV
63323054011	Heparin Sodium 10,000USP 10mL MDV
63323054057	Heparin Sodium 10,000USP 10mL MDV NOVAPLUS
63323054201	Heparin Sodium 10,000USP 1mL MDV
63323027602	Heparin Sodium 2,000USP 2mL SDV
63323091501	Heparin Sodium 20,000USP 1mL MDV
63323054031	Heparin Sodium 30,000USP 30mL MDV
63323045909	Heparin Sodium 40,000USP 4mL MDV
63323054302	Heparin Sodium 5,000USP 0.5mL SDV
63323026201	Heparin Sodium 5,000USP 1mL MDV
63323026255	Heparin Sodium 5,000USP 1mL MDV NOVAPLUS
63323004710	Heparin Sodium 50,000USP 10mL MDV
63323054207	Heparin Sodium 50,000USP 5mL MDV

Table 2

Heparin Sodium Injection in FreeFlex® Bags	
NDC	Description
63323051774	Heparin Sodium 25,000USP 250mL Freeflex Inj. in 0.45% Sodium Chloride
63323051877	Heparin Sodium 25,000USP 500mL Freeflex Inj. in 0.45% Sodium Chloride
63323052374	Heparin Sodium 25,000USP 250mL Freeflex Inj. in 5% Dextrose
63323052277	Heparin Sodium 25,000USP 500mL Freeflex Inj. in 5% Dextrose

Table 3

Heparin Sodium Injection in Simplist® Syringes	
NDC	Description
6332311805	Simplist® Heparin Sodium Injection 5,000USP 0.5 mL PFS
7604510810	Simplist® Heparin Sodium Injection 5,000USP 1 mL PFS

Table 4

Heparin Lock Flush Solution, USP	
NDC	Description
6332354505	Heparin Lock Flush 500USP 5mL MDV
6332354501	Heparin Lock Flush 100USP 1mL MDV
6332354901	Heparin Lock Flush 100USP 1mL SDV