

Re: Lovenox[®] (Enoxaparin Sodium) Pre-filled Syringe Label Adherence Information.

Dear Healthcare Provider:

Sanofi-aventis U.S. is committed to the safety of patients and healthcare professionals who administer our medications.

Sanofi-aventis is aware that certain labels on Lovenox (enoxaparin sodium) 30 mg and 40 mg pre-filled syringes may not fully adhere to the syringe barrel. Additionally, we have received a limited number of reports of needle sticks to healthcare professionals administering the drug to patients reportedly as a result of the label adherence issue. We have determined that this label adherence issue does not affect the integrity or quality of Lovenox in its administration to patients.

We have conducted a preliminary investigation into the label adherence issue and are taking the required steps to address the issue(s) that were identified regarding this matter during the investigation. This label adherence issue is limited to the 30 mg and 40 mg pre-filled syringes.

Communication with healthcare professionals involved in the administration of Lovenox is key to reinforcing use of the safety device in all Lovenox pre-filled syringes to prevent unintended needle sticks. This safety device is activated by firmly pushing the plunger rod after the injection has been administered. A protective sleeve will automatically cover the needle and an audible “click” will be heard to confirm shield activation. Careful injection techniques and ensuring the activation of the safety device, consistent with information in the product labeling (Section 2.4), should reduce the risk of needle sticks.

Additionally, the syringe should be inspected before removing the needle shield. If the product label is not fully affixed to the syringe barrel, caution should be exercised by healthcare professionals before and after administering the injection. After administration, firmly push the plunger rod to deploy the protective sleeve before attempting any additional maneuver. Also, refer to section 2.4 Administration of the US Prescribing Information, specifically *Subcutaneous Injection Technique*, for proper injection technique.

Sanofi-aventis remains committed to providing you with product information to help ensure safe and effective use of Lovenox. If you have any questions or require additional medical information pertaining to Lovenox, please contact sanofi-aventis Medical Information Services at 1-800-633-1610 from 8am to 8pm (EST) Monday-Friday.

Enclosures: Lovenox Full Prescribing Information