

<IMPORTANT SAFETY ADVISORY>

Needlestick injury due to label issue with Lovenox Unit Dose injection

ISMP received a report about a nurse at a large health system who was stuck by a needle on a commercially-prepared **LOVENOX** (enoxaparin) prefilled syringe (sanofi-aventis). The manufacturer's label that was placed around the barrel of the syringe (see Figure 1) did not fully adhere. The needlestick occurred after the nurse had given the patient the injection. Upon removal of the needle from the patient's skin and just before the built-in safety shield could be engaged, the adhesive caught the nurse's glove and twisted the syringe, allowing the needle to stick her.

The reporter told us that additional loose labels have been found on other syringes, while still in their original blister packaging. Syringes from four different lots of Lovenox 40 mg and two lots of 30 mg shipped to the hospital were involved. Some additional Lovenox syringes purchased from a wholesaler or received directly from the company were also affected. ISMP has also learned that the label problem has been identified at other hospitals.

We have contacted the manufacturer, sanofi-aventis. At this time, the company will only acknowledge that

they are aware of the reported needlestick due to the label issue. They said they are currently investigating and will take required steps to address any issue that is identified during the investigation. For questions regarding Lovenox, please contact sanofi-aventis Medical Information Services at 1-800-633-1610. Please report any similar findings to the company.

Because of the serious nature of potential needlestick injuries, we feel it is necessary to forward this alert without delay. As a temporary measure, the hospital mentioned above has created an auxiliary warning label for the outer package to caution nurses about this problem. A photograph of that label appears in Figure 2. Nursing leadership at the hospital has been made aware of the situation so they can follow up with staff.

For hospitals and other healthcare settings where unit dose syringes of Lovenox are

used, ISMP is recommending that pharmacy and nursing staff be made aware of the situation so that syringes can be examined in order to identify any loose labels prior to removing the syringes from the packaging. We expect that further word will be forthcoming from the manufacturer.



Figure 1. Example of syringe label with edges that no longer adhere to syringe.

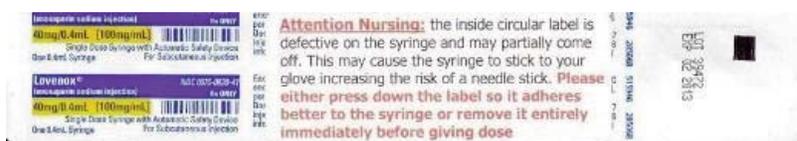


Figure 2. Auxiliary label prepared by hospital for Lovenox and attached to syringe package.