Sagent – Recall of heparin sodium injection

- On February 28, 2023, Sagent announced a consumer-level recall of one lot of heparin sodium injection due to mislabeling on the back panel of the secondary carton. The incorrect labeling omits the preservative and states the incorrect concentration, showing "each mL contains: 1,000 USP units heparin sodium; 9 mg sodium chloride" instead of **the correct labeling, which should state, "each mL contains: 20,000 USP units heparin sodium; 0.01 mL benzyl alcohol (as preservative)."**
    - Other heparin injection products that are not being recalled are available for use.
- The recalled product was distributed from June 2022 to January 2023.

Product Description	NDC#	Lot# (Expiration Date)
Heparin sodium injection, 20,000 USP units per mL	25021-404-01	WP201 (2/2024)

- Heparin sodium injection is indicated for:
    - Prophylaxis and treatment of venous thrombosis and pulmonary embolism;
    - Prevention of postoperative deep venous thrombosis and pulmonary embolism in patients undergoing major abdominothoracic surgery or who, for other reasons, are at risk of developing thromboembolic disease;
    - Atrial fibrillation with embolization;
    - Treatment of acute and chronic consumptive coagulopathies (disseminated intravascular coagulation);
    - Prevention of clotting in arterial and cardiac surgery;
    - Prophylaxis and treatment of peripheral arterial embolism;
    - Anticoagulant use in blood transfusions, extracorporeal circulation, and dialysis procedures.
- Due to the incorrect concentration of 1,000 USP units per mL instead of 20,000 USP units per mL, there is a risk that a higher dose than intended may be administered if a healthcare provider uses the back panel of the secondary carton rather than the primary vial label or Prescribing Information insert to calculate the dose by concentration per mL. This could lead to significant health consequences that would require medical intervention to reverse the heparin effect.
- Additionally, there is a remote probability that the heparin with benzyl alcohol could inadvertently be administered to a premature neonate, infant, or patient with benzyl alcohol allergies which could lead to serious adverse events.
- Patients who are currently using the recalled heparin injection should stop use and contact their pharmacy for a replacement. Patients should contact their physician or healthcare provider if they have experienced any problems that may be related to using the recalled heparin injection.
- Anyone with an existing inventory of the recalled product should stop use, distribution, and quarantine the product immediately and arrange for return.
- Contact Sagent at **1-866-625-1618** for questions regarding this recall.