

FDA Recall – Fresenius Kabi Morphine Sulfate Injection

Purpose of this communication:

We are writing to inform you that Fresenius Kabi has issued a voluntary nationwide recall of one lot of Morphine Sulfate Injection USP, Simplist® 2 mg/1 mL due to a label mix-up. The MicroVault labeled as Morphine Sulfate Injection 2 mg/1 mL may contain a prefilled syringe of Dilaudid (hydromorphone HCl) 0.5 mg/0.5 mL. The impacted product is lot 6402820, expiration date 12/2028, product code 764411, unit-of-use NDC 76045-004-01, and unit-of-sale NDC 76045-004-11, shipped nationwide to distributors and wholesalers between 01/29/2026 and 06/09/2026.

Use of a MicroVault labeled as Morphine Sulfate Injection that contains Dilaudid has a reasonable probability of causing serious adverse health consequences, including life-threatening respiratory depression and death. Patients at greatest risk include individuals who do not use opioids regularly, patients with underlying respiratory disease, pediatric patients, and patients taking central nervous system depressants. As of the recall notice, Fresenius Kabi has not received any adverse event reports for this lot number.

What do I need to do?

- Please review the following recall notice [here](#).
- Immediately discontinue distributing, dispensing, or using the affected lot and return all units to Fresenius Kabi according to the manufacturer's recall instructions. Distributors should immediately notify customers who were shipped or may have been shipped the recalled product.
- Confirm whether any CareCentrix patients may have been affected by this recall and notify the CareCentrix Quality Department by faxing information to: 919-792-6718 Attn: Quality Department.

Thank you in advance for your cooperation and continued partnership.