

Fresenius Kabi – Recall of fluphenazine decanoate injection

- On March 16, 2017, [Fresenius Kabi announced](#) a user level recall of some lots of [fluphenazine decanoate](#) 25 mg/mL injection due to out-of-specification (OOS) results for a 13 month stability test of a specific lot. Additional lots may be OOS prior to expiry due to the common use of a supplier lot of active pharmaceutical ingredient.
- Affected products were distributed between September 1, 2015 and January 16, 2017.

Product Description	NDC #	Lot # (Expiration date)
Fluphenazine decanoate injection, USP 25 mg/mL, 5 mL fill in a 5 mL vial	63323-272-05	6111141 (7/2017), 6111222 (8/2017), 6112346 (1/2018), 6112725 (3/2018)

- Fluphenazine decanoate injection is a long-acting parenteral antipsychotic drug intended for use in the management of patients requiring prolonged parenteral neuroleptic therapy (eg, chronic schizophrenics).
- Fresenius Kabi's health hazard evaluation concluded that the OOS assay value observed is unlikely to be clinically significant. To date, Fresenius Kabi has not received any adverse events reports related to the recalled product.
- Healthcare providers, distributors and wholesalers should immediately check inventory, quarantine, discontinue distribution, and return all recalled product.
- For questions regarding this recall, contact Fresenius Kabi at **1-866-716-2459**.
- For clinical questions or to report adverse events related to this recall, contact the Fresenius Kabi Vigilance and Medical Affairs department at **1-800-551-7176**.