



Drug Recall

DATE OF RECALL: December 31, 2019

DRUG NAME: Mirtazapine 7.5mg & 15mg Tablets

RECALLING FIRM: Aurobindo Pharma USA, Inc.

REASON FOR RECALL: This recall is being issued due to a missing or broken retainer ring which helps to lock the insulin cartridge into place in the pump's reservoir compartment. If the cartridge is not locked firmly into place, under or over delivery of insulin may occur, which could result in hypoglycemia or hyperglycemia.

FDA LINK: This recall is being issued due to a label error on declared strength; bottles labeled as Mirtazapine 7.5 mg may contain 15 mg tablets.

OTHER DETAILS: N/A

RECALLED PRODUCT:

Product Description	NDC Number	Affected Lots/Expire Date
Mirtazapine 7.5 mg Tablets	13107-0001-05	03119002A3 exp. 03/2022
Mirtazapine 15 mg Tablets	13107-0031-05	03119002A3 exp. 03/2022