Drug Recall

DATE OF RECALL: September 15, 2020

DRUG NAME: Amiodarone Hydrochloride Injection and Tranexamic Acid Injection

RECALLING FIRM: Mylan Institutional LLC

REASON FOR RECALL: This recall was issued due to a label mix-up. There is a potential for cartons labeled as Tranexamic Acid Injection to contain vials of Amiodarone HCl Injection and cartons labeled as Amiodarone HCl Injection to contain vials of Tranexamic Acid Injection..

FDA LINK: https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/mylan-initiates-voluntary-nationwide-recall-four-lots-amiodarone-hcl-injection-usp-and-tranexamic

OTHER DETAILS: See FDA link.

RECALLED PRODUCT:

Product Description	NDC Number	Affected Lots	Expiration Date
Amiodarone Hydrochloride Injection, 450 mg/9 mL, 9 mL Single-Dose Vial	67457-0153-99	191207	11/2021
Amiodarone Hydrochloride Injection, 450 mg/9 mL, 10 x 9 mL Single-Dose Vials per Carton	67457-0153-09	191221	11/2021
Tranexamic Acid Injection 1000 mg/10 mL, 10 mL Single-Dose Vial	67457-0197-00	191223	11/2021
Tranexamic Acid Injection 1000 mg/10 mL, 10 x 10 mL Single-Dose Vials per Carton	67457-0197-10	200120	12/2021