

*The Board of Pharmacy has received notice of the following product recall. The Board strongly encourages pharmacies to immediately review their quality assurance and recall policies and procedures to determine if any corrective action is required.*

Amgen has initiated a recall involving sixty-three (63) lots of US Corlanor® (ivabradine) and three (3) lots of US Sensipar® (cinacalcet hydrochloride) tablets. The recall includes the following presentations:

- Corlanor® (ivabradine) 5 mg, 60 tablets in 1 bottle; NDC 55513-800-60
- Corlanor® (ivabradine) 5 mg, 14 tablets in 1 bottle; NDC 55513-800-99
- Corlanor® (ivabradine) 5 mg, 60 tablets in 1 bottle; NDC 55513-810-60
- Sensipar® (cinacalcet hydrochloride) 30 mg, 30 tablets in 1 bottle; NDC 55513-073-30
- Sensipar® (cinacalcet hydrochloride) 60 mg, 30 tablets in 1 bottle; NDC 55513-074-30
- Sensipar® (cinacalcet hydrochloride) 90 mg, 30 tablets in 1 bottle; NDC 55513-075-30

This recall has been initiated due to a low frequency event of an unexpected foreign matter in the reserve sample of one of the identified lots. The unexpected foreign matter was localized on the exterior tablet surface, over the coating. Therefore, as a precautionary measure, all lots within expiry that were processed in AML Building 23 packaging area, where the condition occurred, are being recalled. Health Hazard Assessments addressing worst case scenarios concluded that medical impact and physical hazard associated with the identified foreign material do not pose a clinical risk to patients, and the overall patient safety risk is low. There have been no reports of product complaints associated with this condition.

This recall is being conducted with the knowledge of the U.S. Food and Drug Administration. The products in scope of this recall were distributed in the United States from 10/28/2021 to 12/30/2025.

The following Lot numbers of Corlanor® (ivabradine) and Sensipar® (cinacalcet hydrochloride) tablets are in scope of this important notification:

**Table 1: Detailed Lot Listing - Corlanor**

<b>Material Description</b>	<b>Lot Number</b>	<b>Expiration Date</b>	<b>Distribution Dates</b>
998 FDP US/PR+ 5mg 60TBL BT	1138201	8/31/2026	11/11/2021
998 FDP US/PR+ 5mg 60TBL BT	1138202	8/31/2026	12/16/2021
998 FDP US/PR+ 7.5mg 60TBL BT	1138203	7/31/2026	10/28/2021

998 FDP US/PR+ 5mg 60TBL BT	1138900	8/31/2026	1/13/2022
998 FDP US/PR+ 5mg 14TBL BT NFS	1138901	8/31/2026	4/4/2022
998 FDP US/PR+ 5mg 60TBL BT	1140280	10/31/2026	1/31/2022
998 FDP US/PR+ 5mg 60TBL BT	1140281	10/31/2026	3/10/2022
998 FDP US/PR+ 5mg 60TBL BT	1141143	8/31/2026	1/31/2022
998 FDP US/PR+ 5mg 60TBL BT	1142062	11/30/2026	6/2/2022
998 FDP US/PR+ 5mg 60TBL BT	1142063	10/31/2026	3/7/2022
998 FDP US/PR+ 7.5mg 60TBL BT	1142065	7/31/2026	2/3/2022
998 FDP US/PR+ 5mg 60TBL BT	1142942	11/30/2026	4/11/2022
998 FDP US/PR+ 5mg 60TBL BT	1142943	11/30/2026	6/27/2022
998 FDP US/PR+ 5mg 60TBL BT	1144081	12/31/2026	7/25/2022
998 FDP US/PR+ 5mg 60TBL BT	1144104	12/31/2026	8/11/2022
998 FDP US/PR+ 7.5mg 60TBL BT	1145151	2/28/2027	7/7/2022
998 FDP US/PR+ 7.5mg 60TBL BT	1145152	2/28/2027	5/16/2022
998 FDP US/PR+ 7.5mg 60TBL BT	1145153	2/28/2027	12/14/2022
998 FDP US/PR+ 5mg 60TBL BT	1146373	1/31/2027	7/14/2022
998 FDP US/PR+ 5mg 60TBL BT	1146374	1/31/2027	10/18/2022
998 FDP US/PR+ 5mg 60TBL BT	1147491	3/31/2027	10/17/2022
998 FDP US/PR+ 5mg 60TBL BT	1147492	3/31/2027	11/22/2022

998 FDP US/PR+ 7.5mg 60TBL BT	1148908	5/31/2027	1/3/2023
998 FDP US/PR+ 7.5mg 60TBL BT	1148909	5/31/2027	4/10/2023
998 FDP US/PR+ 5mg 60TBL BT	1149843	3/31/2027	12/28/2022
998 FDP US/PR+ 5mg 14TBL BT NFS	1149846	4/30/2027	1/23/2023
998 FDP US/PR+ 5mg 60TBL BT	1151113	7/31/2027	5/18/2023
998 FDP US/PR+ 5mg 60TBL BT	1151114	9/30/2027	7/17/2023
998 FDP US/PR+ 5mg 60TBL BT	1151115	9/30/2027	8/21/2023
998 FDP US/PR+ 5mg 60TBL BT	1151890	7/31/2027	6/26/2023
998 FDP US/PR+ 5mg 60TBL BT	1152412	6/30/2027	3/20/2023
998 FDP US/PR+ 5mg 60TBL BT	1153399	6/30/2027	12/19/2022
998 FDP US/PR+ 5mg 60TBL BT	1153400	6/30/2027	3/6/2023
998 FDP US/PR+ 5mg 60TBL BT	1153401	7/31/2027	5/15/2023
998 FDP US/PR+ 5mg 60TBL BT	1155834	4/30/2027	2/6/2023
998 FDP US/PR+ 5mg 60TBL BT	1155835	4/30/2027	1/23/2023
998 FDP US/PR+ 5mg 60TBL BT	1155836	9/30/2027	8/17/2023
998 FDP US/PR+ 5mg 60TBL BT	1158480	10/31/2027	9/25/2023
998 FDP US/PR+ 5mg 60TBL BT	1158481	10/31/2027	10/19/2023
998 FDP US/PR+ 5mg 60TBL BT	1158482	10/31/2027	10/26/2023
998 FDP US/PR+ 5mg 60TBL BT	1160354	3/31/2028	12/26/2023
998 FDP US/PR+ 5mg 60TBL BT	1160355	3/31/2028	12/12/2023
998 FDP US/PR+ 5mg 60TBL BT	1161593	4/30/2028	3/11/2024

998 FDP US/PR+ 5mg 60TBL BT	1161594	4/30/2028	4/15/2024
998 FDP US/PR+ 5mg 60TBL BT	1161595	4/30/2028	12/26/2023
998 FDP US/PR+ 7.5mg 60TBL BT	1162845	11/30/2027	9/7/2023
998 FDP US/PR+ 7.5mg 60TBL BT	1162846	11/30/2027	10/5/2023
998 FDP US/PR+ 5mg 60TBL BT	1164097	6/30/2028	5/30/2024
998 FDP US/PR+ 5mg 60TBL BT	1164098	6/30/2028	1/29/2024
998 FDP US/PR+ 5mg 60TBL BT	1164099	6/30/2028	7/1/2024
998 FDP US/PR+ 5mg 60TBL BT	1165078	7/31/2028	3/18/2024
998 FDP US/PR+ 5mg 60TBL BT	1165079	7/31/2028	4/15/2024
998 FDP US/PR+ 5mg 60TBL BT	1165080	2/29/2028	11/27/2023
998 FDP US/PR+ 7.5mg 60TBL BT	1166471	5/31/2028	2/15/2024
998 FDP US/PR+ 7.5mg 60TBL BT	1166472	5/31/2028	5/6/2024
998 FDP US/PR+ 7.5mg 60TBL BT	1166473	5/31/2028	6/17/2024
998 FDP US/PR+ 5mg 60TBL BT	1168005	9/30/2028	6/17/2024
998 FDP US/PR+ 5mg 60TBL BT	1168006	9/30/2028	11/14/2024
998 FDP US/PR+ 5mg 60TBL BT	1168007	9/30/2028	3/31/2025
998 FDP US/PR+ 5mg 60TBL BT	1169288	10/31/2028	7/22/2024
998 FDP US/PR+ 5mg 60TBL BT	1169289	10/31/2028	4/21/2025
998 FDP US/PR+ 7.5mg 60TBL BT	1170615	8/31/2028	3/3/2025
998 FDP US/PR+ 5mg 60TBL BT	1172885	12/31/2028	9/15/2025

**Table 2:** Detailed Lot Listing - **Sensipar**

<b>Material Description</b>	<b>Lot Number</b>	<b>Expiration Date</b>	<b>Distribution Dates</b>
038 FDP US/PR+ 30mg 30TBL	1156858	12/31/2027	6/6/2023
038 FDP US/PR+ 60mg 30TBL	1157055	1/31/2028	6/6/2023
038 FDP US/PR+ 90mg 30TBL	1157056	2/29/2028	8/21/2023