

*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.*

This is to inform you of a product recall by Cipla USA, Inc. for 32 lot numbers of Lanreotide Injection 120mg/0.5ml. The product is labeled for and marketed by Cipla USA, Inc. bearing the NDC Numbers 69097-0870-67.

The recall is due to an FDA observation at the contract manufacturing site for deficiencies in their visual inspection procedure.

Based on Health Hazard Evaluation, although quantitative data on particulate mass per unit, or tested sample in general were not available, the test findings are described as isolated, inert materials (e.g., PTFE, elastomers, stainless steel, intrinsic APT). Even under conservative worst case assumptions, the potential exposure to such inorganic particulates would remain several orders of magnitude below the established Threshold of Toxicological Concern (TTC) values typically applied by regulatory agencies for unintentionally introduced impurities in parenteral products. Given the extremely low frequency of occurrence and the negligible mass of individual particulates, the overall exposure would be far below thresholds associated with systemic toxicological concern.

Based on these observations, it is concluded that the exposure of the product with observed non conformance is not likely to cause adverse health consequences.

No.	Product Name	Batch Number	Expiry Date	Dates Distributed
1.	Lanreotide Injection 120mg/0.5ml	4301954IR1	31/10/2026	06/07/2024-06/14/2024
2.	Lanreotide Injection 120mg/0.5ml	4301994IR1	31/10/2026	06/14/2024-06/18/2024
3.	Lanreotide Injection 120mg/0.5ml	4301995IR1	31/10/2026	07/30/2024-08/02/2024
4.	Lanreotide Injection 120mg/0.5ml	4301996IR1	31/10/2026	06/12/2024-06/21/2024

5.	Lanreotide Injection 120mg/0.5ml	4400005IR1	30/11/2026	06/25/2024- 06/28/2024
6.	Lanreotide Injection 120mg/0.5ml	4400006IR1	30/11/2026	07/18/2024- 07/19/2024
7.	Lanreotide Injection 120mg/0.5ml	4400007IR1	30/11/2026	06/21/2024- 06/25/2024
8.	Lanreotide Injection 120mg/0.5ml	4400124IR1	30/11/2026	07/15/2024- 07/17/2024
9.	Lanreotide Injection 120mg/0.5ml	4400154IR1	30/11/2026	06/28/2024- 07/03/2024
10.	Lanreotide Injection 120mg/0.5ml	4400155IR1	30/11/2026	07/12/2024- 07/12/2024
11.	Lanreotide Injection 120mg/0.5ml	4400156IR1	30/11/2026	07/03/2024- 07/12/2024
12.	Lanreotide Injection 120mg/0.5ml	4400373IR1	31/12/2026	07/29/2024- 07/30/2024
13.	Lanreotide Injection 120mg/0.5ml	4400374IR1	31/12/2026	07/12/2024- 07/29/2024
14.	Lanreotide Injection 120mg/0.5ml	4400374IR1	31/12/2026	08/20/2024- 08/30/2024
15.	Lanreotide Injection 120mg/0.5ml	4400455IR1	31/1/2027	10/31/2024- 11/21/2024

16.	Lanreotide Injection 120mg/0.5ml	4400456IR1	31/1/2027	08/19/2024- 10/24/2024
17.	Lanreotide Injection 120mg/0.5ml	4400457IR1	31/1/2027	08/08/2024- 09/25/2024
18.	Lanreotide Injection 120mg/0.5ml	4400544IR1	28/2/2027	10/24/2024- 11/21/2024
19.	Lanreotide Injection 120mg/0.5ml	4400606IR1	28/2/2027	11/22/2024- 11/22/2024
20.	Lanreotide Injection 120mg/0.5ml	4400607IR1	28/2/2027	12/21/2024- 12/22/2024
21.	Lanreotide Injection 120mg/0.5ml	4400696IR1	28/2/2027	11/22/2024- 12/13/2024
22.	Lanreotide Injection 120mg/0.5ml	4400697IR1	28/2/2027	01/14/2025- 01/17/2025
23.	Lanreotide Injection 120mg/0.5ml	4400779IR1	28/2/2027	12/13/2024- 12/20/2025
24.	Lanreotide Injection 120mg/0.5ml	4400780IR1	28/2/2027	12/20/2024- 12/20/2024
25.	Lanreotide Injection 120mg/0.5ml	4400781IR1	28/2/2027	12/20/2024- 12/23/2024

26.	Lanreotide Injection 120mg/0.5ml	4400844IR1	31/3/2027	01/23/2025- 01/27/2025
27.	Lanreotide Injection 120mg/0.5ml	4400845IR1	31/3/2027	12/23/2024- 12/23/2024
28.	Lanreotide Injection 120mg/0.5ml	4400849IR1	31/3/2027	02/05/2025- 02/13/2025
29.	Lanreotide Injection 120mg/0.5ml	4400984IR1	31/3/2027	12/23/2024- 02/26/2025
30.	Lanreotide Injection 120mg/0.5ml	4400985RIR	31/3/2027	01/27/2025- 01/30/2025
31.	Lanreotide Injection 120mg/0.5ml	4400986IR1	31/3/2027	01/30/2025- 02/05/2025
32.	Lanreotide Injection 120mg/0.5ml	4401023IR1	31/3/2027	01/13/2025- 01/17/2025