

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 communication is to notify you that Zydus Pharmaceuticals (USA) Inc. ("Zydus"), is recalling the drug product mentioned in the table below at the **Retail Level**.

This recall has been initiated due to product complaints reporting brown/red dots or spots inside capsules and/or capsules adhering to one another. The reason for observed appearance was determined to result from oxidation caused by leakage of the contents of the Icosapent Ethyl Capsules 1g. Use of the affected product may lead to inconsistent therapeutic effects and potential gastrointestinal side effects in some patients.

The product was shipped to our customers from Apr 03, 2025 to Feb 16, 2026.

| Sr. No. | Product and Strength | NDC Number | Lot Number | Exp. Date | Pack size | Distribution Start Date | Distribution End Date |
|----------------|------------------------------|-------------------|-------------------|------------------|----------------------------------|--------------------------------|------------------------------|
| 1 | Icosapent Ethyl Capsules 1 g | 70710-1592-07 | S2520249 | 2027/Jan | 120's Count Bottle Pack | 04/03/2025 | 04/04/2025 |
| 2 | Icosapent Ethyl Capsules 1 g | 70710-1592-07 | S2520250 | 2027/Jan | 120's Count Bottle Pack | 04/04/2025 | 05/05/2025 |
| 3 | Icosapent Ethyl Capsules 1 g | 70710-1592-07 | S2520267 | 2027/Jan | 120's Count Bottle Pack | 05/06/2025 | 05/30/2025 |
| 4 | Icosapent Ethyl Capsules 1 g | 70710-1592-07 | S2520303 | 2027/Feb | 120's Count Bottle Pack | 05/24/2025 | 08/15/2025 |
| 5 | Icosapent Ethyl Capsules 1 g | 70710-1592-07 | S2520305 | 2027/Feb | 120's Count Bottle Pack | 07/07/2025 | 08/25/2025 |
| 6 | Icosapent Ethyl Capsules 1 g | 70710-1592-07 | S2520332 | 2027/Feb | 120's Count | 08/22/2025 | 10/03/2025 |

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|---|---------------------------------|-------------------|----------|----------|--|------------|------------|
| 7 | Icosapent Ethyl Capsules 1 g | 70710- 1592-07 | S2540208 | 2027/Apr | Bottle Pack 120's Count Bottle Pack | 12/12/2025 | 01/09/2026 |
| 8 | Icosapent Ethyl Capsules 1 g | 70710- 1592-07 | S2540209 | 2027/Apr | 120's Count Bottle Pack | 01/09/2026 | 02/16/2026 |