XGen Pharmaceuticals – Recall of cyclophosphamide injection

- On April 3, 2024, XGen Pharmaceuticals announced a consumer level recall of two lots of cyclophosphamide injection because there was an error on the Physician's Insert (PI), section 2.3, Preparation, Handling, and Administration. The concentration of the reconstituted product is listed as "20 mg per vial." This information should read: "20 mg per mL."
    - The units for strength (mg) of the lyophilized product and dilutions (mL) are stated correctly. This error might lead to a miscalculation of dosage for administration.
- Cyclophosphamide was distributed nationwide between January 26, 2024 and March 26, 2024.

Product Description	NDC#	Lot# (Expiration Date)
Cyclophosphamide for Injection, 500 mg	39822-0250-1	CIC123001A (8/21/2026)
Cyclophosphamide for Injection, 1 gm	39822-0255-1	CIC223001A (11/30/2026)

- Cyclophosphamide is indicated for the treatment of malignant lymphomas, Hodgkins disease, lymphocytic lymphoma, mixed-cell type lymphoma, histiocytic lymphoma, Burkitts lymphoma, multiple myeloma, leukemias, mycosis fungoides, neuroblastoma, adenocarcinoma of the ovary, retinoblastoma, carcinoma of the breast, and treatment of biopsy proven minimal change nephrotic syndrome in pediatric patients.
- Anyone with the affected lots on hand should stop distribution and return product. Patients should contact their healthcare provider with any medical related questions.
- Contact XGen by phone at 1-607-562-2700 or by email at **recall@xgenpharmadjb.com** for questions regarding this recall.