Teva – Recall of Idarubicin injection

- On March 29, 2022, Teva announced a user-level recall of one lot of idarubicin injection because of particulate matter, identified as silica and iron oxide, found in one vial.
- The following product was distributed nationwide from December 4, 2020, through August 18, 2021.

Product Description	NDC#	Lot# (Expiration Date)
Idarubicin hydrochloride injection 5 mg/5 mL vial	0703-4154-11	31329657B (08/2023)

- Idarubicin in combination with other approved anti-leukemic drugs is indicated for the treatment of acute myeloid leukemia in adults.
- The administration of an injectable product that contains particulate matter may result in local irritation or swelling in response to the foreign material. If the particulate matter reaches the blood vessels it can travel to various organs and block blood vessels in the heart, lungs or brain which can cause stroke and even lead to death.
- While the health hazard risk could be severe if particulate matter is infused, Teva's internal health assessment determined that the likelihood of patient harm is remote or unlikely.
- To date, Teva has received no product quality complaints or adverse event reports related to the recalled lot.
- Anyone with an existing inventory of the recalled product should stop distribution and quarantine the product immediately.
- Patients should contact their physician or health care provider if they have experienced any problems that may be related to the recalled idarubicin injection.
- Contact Teva Medical Information at **1-888-838-2872**, option 3, then, option 4, or Teva Quality Assurance Services at **1-888-838-2872**, option 4 for more information about the recall.