Endo – Recall of Edex® (alprostadil)

- On February 24, 2017, the FDA announced a voluntary, consumer-level recall of one lot of Endo's Edex (alprostadil) 10 mcg injection due to the detection by Endo of a defect in the crimp caps used in the manufacture of the recalled lot.
- The affected lot was distributed from December 13, 2016 through February 13, 2017.

Product Description	NDC #	Lot # (Expiration Date)
Edex (alprostadil) 10 mcg injection, cartridge 2 pack	52244-010-02	207386 (May 2019)

- Edex is indicated for the treatment of erectile dysfunction due to neurogenic, vasculogenic, psychogenic, or mixed etiology.
- Defects in the crimp cap has the potential to lead to a loss of container closure integrity, which could impact the product's sterility assurance and may lead to serious adverse events such as infections, both localized at the site of injection and systemically.
- To date, Endo has not received adverse event reports related to this recall.
- Healthcare providers, distributors and wholesalers should immediately check inventory, quarantine, and discontinue distribution of the recalled product.
- Consumers in possession of any unused recalled Edex product should immediately discontinue use of the product and contact Inmar at **1-844-529-1586** or **Edex@inmar.com** for return information.
- Consumers who are unsure if they have the affected lot number should consult their pharmacist or healthcare provider.
- For any questions regarding this recall, contact Endo at **1-800-462-3636**.