Naloxone nasal spray – New drug approval

- On March 8, 2023, Amphastar Pharmaceuticals announced the FDA approval of naloxone nasal spray, for emergency treatment of known or suspected opioid overdose, as manifested by respiratory and/or central nervous system depression, for adult and pediatric patients.
    - Naloxone nasal spray is intended for immediate administration as emergency therapy in settings where opioids may be present.
    - Naloxone nasal spray is not a substitute for emergency medical care.
- Other intranasal formulations of naloxone include Narcan® (available generically) and Kloxxado™. Both are also approved for the emergency treatment of known or suspected opioid overdose.
- Warnings and precautions for naloxone nasal spray include risk of recurrent respiratory and central nervous system depression; limited efficacy with partial agonists or mixed agonist/antagonists; and precipitation of severe opioid withdrawal.
- The most common adverse reactions with naloxone nasal spray use were oral paraesthesia and headache.
- The recommended initial dose of naloxone nasal spray in adults and pediatric patients is one spray delivered by intranasal administration, which delivers 4 mg of naloxone.
    - For repeat dosing instructions, refer to the naloxone drug label.
- Amphastar Pharmaceuticals' launch plans for naloxone nasal spray are pending. Naloxone nasal spray will be available as a carton containing two unit-dose naloxone nasal spray devices (each delivers a single spray containing 4 mg of naloxone).