FDA announces shelf-life extension for naloxone nasal spray

Today, FDA is announcing that Emergent BioSolutions is extending the shelf-life of newly manufactured NARCAN (naloxone hydrochloride) 4 milligram (mg) Nasal Spray products from 3-years to 4-years. This action was taken at the request of the FDA and is the latest of multiple steps the Agency has recently taken to prevent overdoses and reduce overdose-related deaths by expanding access to naloxone and other overdose reversal agents.

Naloxone is a medication that rapidly reverses the effects of opioid overdose and is the proven standard treatment for opioid overdose as it is a medicine with no abuse potential, and it is not a controlled substance. NARCAN nasal spray was first approved by the FDA in 2015 as a prescription drug. In March 2023, FDA approved (/news-events/press-announcements/fda-approves-first-over-counter-naloxone-nasal-spray) NARCAN 4 mg nasal spray, as the first naloxone product approved for over-the-counter, nonprescription use. The Agency also approved an initial shelf-life extension for NARCAN 4 mg nasal spray in August 2020 (https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2020/208411Orig1s004ltr.pdf) which extended the original product's shelf-life from 2-years to 3-years.

This shelf-life extension applies only to NARCAN (4 mg) nasal spray products produced following today. The shelf-life of products that were produced and distributed prior to this announcement is not affected and remains unchanged. Prescribers, patients, and caregivers are advised to continue to abide by the expiration date printed on each product's packaging and within the product's labeling.

"Naloxone is an important tool in addressing opioid overdoses. Today's shelf-life extension of newly manufactured lots of Narcan 4 mg nasal spray supports the FDA's Overdose Prevention Framework and efforts to ensure more OTC naloxone products remain available to the public," said Marta Sokolowska, Ph.D., deputy center director for Substance Use and Behavioral Health in FDA's Center for Drug Evaluation and Research.

FDA's request for this shelf-life extension is a testament to the Agency's continuing progress towards implementing the FDA Overdose Prevention Framework (/drugs/drug-safety-and-availability/food-and-drug-administration-overdose-prevention-framework), which provides our vision to undertake impactful, creative actions to encourage harm reduction and innovation in reducing controlled substance-related overdoses and deaths. As we move forward in executing that vision, we remain focused on responding to all facets of substance use, misuse, overdose, and death through the four priorities of the framework, including: supporting primary

prevention by eliminating unnecessary initial prescription drug exposure and inappropriate prolonged prescribing; encouraging harm reduction through innovation and education; advancing development of evidence-based treatments for substance use disorders; and protecting the public from unapproved, diverted, or counterfeit drugs presenting overdose risks.

Additional Resources:

- Information about Naloxone and Nalmefene (/drugs/postmarket-drug-safety-information-patients-and-providers/information-about-naloxone-and-nalmefene)
- FDA Overdose Prevention Framework (/drugs/drug-safety-and-availability/food-and-drug-administration-overdose-prevention-framework)
- Timeline of Selected FDA Activities and Significant Events Addressing Substance Use and Overdose Prevention (/drugs/information-drug-class/timeline-selected-fda-activities-and-significant-events-addressing-substance-use-and-overdose)