

RiVive™ (naloxone) – New over-the-counter approval

- On July 28, 2023, the [FDA announced](#) the approval of [Harm Reduction Therapeutics](#) over-the-counter (OTC) [RiVive \(naloxone\)](#) nasal spray 3 mg, to revive someone during an overdose from many prescription pain medications or street drugs such as heroin.
 - RiVive is the third naloxone product approved for OTC use. [Narcan®](#) by Emergent Biosolutions was the first naloxone OTC product FDA approved in March 2023 and Padagis received [FDA approval](#) of OTC generic Narcan in July 2023.
 - RiVive nasal spray is the first naloxone product approved in a 3 mg strength.
- In accordance with a process to change the status of a drug from prescription to nonprescription, Harm Reduction Therapeutics provided data demonstrating that the drug is safe and effective for use as directed in its proposed labeling. The manufacturer also showed that consumers can understand how to use the drug safely and effectively without the supervision of a healthcare professional.
- The use of RiVive in individuals who are opioid dependent may result in severe opioid withdrawal characterized by body aches, diarrhea, increased heart rate, fever, runny nose, sneezing, goose bumps, sweating, yawning, nausea or vomiting, nervousness, restlessness or irritability, shivering or trembling, abdominal cramps, weakness and increased blood pressure.
- Refer to the RiVive OTC label for a complete description of directions for use.
- Harm Reduction Therapeutics plans to launch RiVive by early 2024. RiVive will be packaged as 2 single-dose nasal spray devices (containing 3 mg each).
 - Harm Reduction Therapeutics plans to distribute RiVive to U.S. harm reduction organizations and state governments for costs lower than other opioid antagonist nasal sprays.
 - Harm Reduction Therapeutics is focused on supplying RiVive to communities who need it most and will make at least 200,000 doses (10% of projected initial annual product production) available for free.