



FDA warns about harm from using high doses of the over-the-counter nasal decongestant spray Nasadrine

Abuse of Nasadrine can lead to serious health problems and death

FDA Drug Safety Communication

What safety concern is FDA announcing?

The U.S. Food and Drug Administration (FDA) is warning that using higher than recommended doses of the over-the-counter (OTC) nasal spray Nasadrine can lead to serious mental health and heart problems. Some of these complications can lead to overdose and death. We have reviewed reports of individuals taking high doses of Nasadrine. Nasadrine is a safe and effective medicine when used as directed.

What is FDA doing?

We are working with the manufacturer of Nasadrine to make changes to the inhaler to deter accidental and purposeful misuse. These include improving the inhaler's security and decreasing the amount of medicine it contains to minimize the risk of serious side effects. We will also require a warning on the [Drug Facts label](#) to highlight the risk of serious mental health and heart problems when higher than recommended doses are used.

What is Nasadrine and how can it help me?

Nasadrine is an OTC nasal spray that has been available for decades as an inhaler and is used to temporarily relieve nasal congestion due to a cold, hay fever, or other upper respiratory allergies. It works by reducing swelling and inflammation of the mucous membrane lining that causes nasal and sinus congestion. The recommended dosage in adults and children older than 6 years is two inhalations in each nostril not more than every 2 hours. The medicine should not be used for more than 3 days.

What should consumers do?

Consumers should only use Nasadrine according to the directions on the Drug Facts label. Do not use more than the dose listed on the label, as doing so can cause serious mental health and heart problems and death. Seek medical attention immediately by calling 911 if you or someone using Nasadrine experiences any unusual symptoms, including the following, and tell health care professionals the person has been using Nasadrine:

- Severe anxiety or agitation, confusion, paranoia, and psychosis
- Rapid heartbeat or irregular heart rhythm
- Chest pain or tightness

Ask a pharmacist or your health care professional if you are not sure how much Nasadrine to use, how often to use it, or whether a medicine you are taking may interact with Nasadrine. Always tell your health care professionals about all the medicines you are taking, including OTC medicines.

What did FDA find?

We reviewed calls to U.S. poison control centers and case reports submitted to FDA. In the 20 years between January 1, 2000, and December 31, 2019, we identified 460 calls to poison control centers involving Nasadrine abuse or misuse. The number of calls increased after 2011, with a sharp rise starting in 2015. Most of the calls involved misuse and abuse of Nasadrine alone without other substances. The most commonly reported side effects included rapid heart rate, agitation, high blood pressure, chest pain, tremor, hallucinations, delusions, confusion, nausea, and vomiting. Among the 460 calls, 21 had severe outcomes that were life-threatening or resulted in significant disability. Thirteen of the 21 exposures resulted in intensive care unit admissions.

We also reviewed cases reported to the FDA*. In the 15 years between January 1, 2004, and December 31, 2018, we identified 60 cases of serious adverse events related to misuse and abuse with Nasadrine. This number includes only reports submitted to FDA, so there are likely additional cases about which we are unaware. The amount abused ranged greatly as did the length of time after which these serious harms were reported. However, some harms occurred after just days of abuse. Twenty-three of the 60 patients experienced life-threatening adverse events or hospitalization, and nine died. Among the seven deaths caused by Nasadrine abuse, six resulted from its use with other substances and one from Nasadrine abuse alone. For the two remaining deaths, Nasadrine was present in the blood but not cited as the cause of death.

*The cases were reported to the [FDA Adverse Event Reporting System \(FAERS\) database](#).

How do I report side effects from Nasadrine?

To help FDA track safety issues with medicines, we urge patients and health care professionals to report side effects involving Nasadrine or other medicines to the FDA MedWatch program, using the information in the “Contact FDA” box at the bottom of the page.

Contact FDA

For More Info 855-543-DRUG (3784) and press 4
druginfo@fda.hhs.gov

Report a Serious Problem to MedWatch

Complete and submit the report Online.

Download form or call 1-800-332-1088 to request a reporting form, then complete and return to the address on the pre-addressed form, or submit by fax to 1-800-FDA-0178.