FDA issues warning about propylhexedrine abuse, misuse

The Food and Drug Administration (FDA) is warning health care providers about risks related to abuse/misuse of propylhexedrine, an over-the-counter nasal decongestant inhaler. Serious harm can occur, including abnormal heart rhythm, high blood pressure and paranoia and death.

The inhaler (sold under the brand Benzedrex) is labeled for adults and children 6 years and up. The dosage is two inhalations in each nostril not more than every two hours and the product should not be used more than three days in a row.

The FDA reviewed 415 cases of propylhexedrine abuse and 45 cases of misuse documented by the U.S. Poison Control Center between Jan. 1, 2000, and Dec. 31, 2019. Individuals ranged in age from 12 to 68 years, and most were males. The FDA also received 53 voluntary reports from 1969-2020 and seven cases of serious adverse events from emergency department visits between 2016 and 2018. Findings in an FDA review of 49 case reports and an observational study also were similar to the cases identified from poison control calls, emergency department visits and voluntary reports to the FDA.

Because there is no reversal agent for acute intoxication, symptomatic and supportive care should be provided, according to the FDA. Major issues that may have to be managed include severe agitation, tachycardia, hypertension, myocardial infarction, hyperthermia, stroke, bowel obstruction, pulmonary hypertension and seizures. Long-term use can also lead to lung damage, arrhythmias and cardiac damage. The FDA also recommends that health care providers who suspect an overdose assess whether the patient used propylhexedrine with other substances.

Report adverse events or side effects related to the use of these products to the FDA MedWatch Safety Information and Adverse Event Reporting Program at http://bit.ly/FDA_medwatch.