en Español (http://esp.fda.gov/TobaccoProducts/default.htm)

Some E-cigarette Users Are Having Seizures, Most Reports Involving Youth and Young Adults



The FDA has become aware that some people who use e-cigarettes (/Tobacco-Products/Labeling/ProductsIngredientsComponents/ucm456610.htm) have experienced seizures, with most reports involving youth or young adult users. Seizures or convulsions are known potential side effects of nicotine toxicity and have been reported in the scientific literature in relation to intentional or accidental swallowing of e-liquid. However, a recent uptick in voluntary reports of adverse experiences with tobacco products that mentioned seizures occurring with e-cigarette use (e.g., vaping) signal a potential emerging safety issue. The FDA continues to monitor all adverse experiences reported to the agency about the use of e-cigarettes and encourages the public to report cases of individuals who use e-cigarettes and have had a seizure via the online Safety Reporting Portal (/TobaccoProducts /PublicHealthScienceResearch/ucm377563.htm), as further described below.

Seizures result from sudden, abnormal electrical activity in the brain. Though often associated with convulsions in which a person's entire body shakes uncontrollably, not all seizures show full-body shaking. Other possible signs of seizures include a lapse in awareness or consciousness, which may look like a person is staring blankly into space for a few seconds or suddenly stops moving. The person may or may not fall down. Most seizures end in a few seconds or minutes, and the person may seem fine, sleepy, confused or have a headache afterwards. They may not remember what they were doing or what happened right before the seizure. While seizures generally do not cause lasting harm, they indicate the need for prompt medical attention to look for a cause and to prevent future seizures, if possible. If you think a person is having a seizure, call 911 and seek immediate medical help. For exposures with

less serious visible effects or if you have questions, call poison control at 800-222-1222.

The FDA has been receiving <u>voluntary adverse experience reports (/Tobacco-Products/PublicHealthScienceResearch/ucm581911.htm)</u> about tobacco products since 1988, including accepting online reports since 2014 via the Safety Reporting Portal (SRP). Consumers have also reported adverse experience information directly to poison control centers. Since June 2018, the FDA observed a slight but noticeable increase in reports of seizures. After examining poison control centers' reports between 2010 and early 2019, the FDA determined that, between the poison control centers and the FDA, there were a total of 35 reported cases of seizures mentioning use of e-cigarettes within that timeframe. Due to the voluntary nature of these case reports, there may be more instances of seizure in e-cigarette users than have been reported.

Seizures have been reported among first-time e-cigarette users and experienced users. In a few situations, e-cigarette users reported a prior history of seizure diagnosis. A few reported cases indicated seizures in association with use of other substances such as marijuana or amphetamines. Seizures have been reported as occurring after a few puffs or up to one day after use. Most of the self-reported data that the FDA has received does not contain any specific brand or sub-brand information about the e-cigarette.

While detailed information is currently limited, the FDA is alerting the public to this important and potentially serious health issue.

- Healthcare providers should be aware that seizures may be associated with
 e-cigarette use—<u>redacted reports of past incidents (/downloads/Tobacco-Products/NewsEvents/UCM635154.pdf)</u> are available on the FDA website and may assist medical evaluations of seizures.
- Consumers should recognize the wide range of symptoms that may be associated with e-cigarette use and the importance of reporting new or unexpected seizures to their doctor or clinic.
- Parents, teachers, and other concerned adults should be aware that many youth are using e-cigarettes that closely resemble a USB flash drive, have high levels of nicotine and emissions that are hard to see.
- Youth and young adult users should also be aware that some e-cigarettes (also called vapes) can contain high levels of nicotine, even as much nicotine as a pack of regular cigarettes. Teens who vape may end up addicted to nicotine faster than teens who smoke. Vapes may be used more frequently because they are easier to hide and may expose users to more nicotine. There are no safe tobacco products.

The FDA is seeking more information about seizures following e-cigarette use to identify common risk factors and understand if any e-cigarette product attributes such as nicotine content or formulation may contribute to seizures. If you or someone you know experiences any unexpected health or safety issues with any tobacco product, please report it through the Safety Reporting Portal (SRP). SRP users may upload relevant medical records in support of or instead of a full SRP report.

When reporting an adverse experience, please be sure to include:

- The name of the manufacturer
- The brand name, model, and serial number of the device or e-liquid, if applicable
- Where the device or e-liquid was purchased
- Whether the device or e-liquid was modified in any way or whether there was a device malfunction
- Whether other tobacco products, medications, supplements or other substances were used
- Whether there were any other symptoms (i.e., nausea, vomiting) or warning right before the adverse experience, such as change in the user's behavior, alertness, vision or hearing
- Details about product use preceding the event (duration, amount and intensity of e-cigarette use)
- Details about health effects, including specific areas of the body affected, how symptoms progressed, how long they lasted, the course of the recovery, and the medical testing or care and decisions rendered

Additional Resources

- CDC Seizure First Aid (https://www.cdc.gov/epilepsy/about/firstaid.htm?CDC AA refVal=https%3A%2F
 %2Fwww.cdc.gov%2Fepilepsy%2Fbasics%2Ffirst-aid.htm)
- Medline Plus Seizures (https://medlineplus.gov/seizures.html)
- <u>Safety Reporting Portal for Tobacco Products (/TobaccoProducts/Pub-licHealthScienceResearch/ucm377563.htm)</u>
- <u>Tobacco Product Problem Reports (/TobaccoProducts/PublicHealth-ScienceResearch/ucm581911.htm)</u>
- Think E-Cigs Can't Harm Teen's Health? (/TobaccoProducts/NewsEvents/ucm633034.htm)
- American Association of Poison Control Centers: Tobacco & Liquid Nicotine Recommendations (https://www.aapcc.org/prevention/tobacco-liquid-nicotine) ☐ (http://www.fda.gov/AboutFDA/AboutThisWebsite/WebsitePolicies /Disclaimers/default.htm)

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