

Pharmacovigilance Drug Safety Communication

Abuse and misuse of propylhexedrine nasal decongestant causes serious harm including heart and mental health problems or death

The FDA issued a Drug Safety Communication (DSC) warning of the risks of serious adverse drug events from the abuse or misuse of propylhexedrine. Propylhexedrine (Benedrex®) is an over-the-counter (OTC) intranasal inhaler for the temporary treatment of nasal congestion. The recommended dose for adults and children older than 6 years is two inhalations in each nostril not more often than every 2 hours for no more than 3 days. Data from the U.S. Poison Control Centers, MedWatch, and published literature highlight the abuse of propylhexedrine alone or with other substances resulting in adverse drug events, some events were life-threatening, resulted in hospitalization, or death.

Abuse and misuse of propylhexedrine has occurred by individuals ingesting or injecting the medication in attempts to feel euphoria or improve productivity. The FDA is requesting manufacturers modify the product design to make tampering with or accessing the medication more difficult or to decrease the amount of medicine in the device. The FDA will continue to evaluate this safety issue and determine if additional actions are needed.



Recommendations for Patients: Only use propylhexedrine according to the instructions on the package label. Do not use it in ways other than inhalation. Seek medical attention immediately for by calling 911 or Poison Control (1-800-222-1222) for anyone using propylhexedrine who experiences:

- Severe anxiety or agitation, confusion, hallucinations, or paranoia
- Rapid heartbeat or abnormal heart rhythm
- Chest pain or tightness

Recommendations for health care professionals:

- Be aware that some individuals are abusing or misusing propylhexedrine.
- In the event of a suspected overdose, attempt to determine whether a patient used propylhexedrine alone or with other substances.
- There is no treatment to reverse the effects of propylhexedrine. In cases of acute intoxication provide symptomatic and supportive care.

The complete Drug Safety Communication can be viewed on the [FDA website](#).

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To help the FDA track safety issues with propylhexedrine, please report adverse events involving this or other medicines to the MedWatch program as recommended in the [Indian Health Manual](#). Instructions for reporting can be found online at the NPTC Pharmacovigilance website.