



The FDA Safety Information and Adverse Event Reporting Program

Over-The-Counter Eye Drops and Nasal Sprays: Drug Safety Communication - Serious Adverse Events From Accidental Ingestion by Children

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美國FDA警示，兒童誤食眼用和鼻用藥品時，造成危及生命的不良事件。這些藥品用於減輕發紅、鼻充血等症狀，活性成分如tetrahydrozoline、oxymetazoline、naphazoline。FDA檢視這些兒童誤食的案例，年齡層為5歲以下兒童；沒有死亡案例，但有嚴重不良事件須送醫治療，包含噁心嘔吐、嗜睡、心跳加速、呼吸減緩、心跳徐緩、低血壓、高血壓、鎮靜、瞳孔放大、體溫下降、昏迷。兒童使用少量(1-2 ml)的眼用鼻用藥品可能導致嚴重不良事件。

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AUDIENCE: Pediatrics, Consumer

ISSUE: FDA is warning healthcare professionals and the public that accidental ingestion by children of over-the-counter eye drops used to relieve redness and nasal decongestant sprays can result in serious and life-threatening adverse events. The eye drops and nasal sprays that have been involved in the cases of accidental ingestion contain the active ingredients tetrahydrozoline, oxymetazoline, or naphazoline. The cases of accidental ingestion reviewed by FDA occurred in children 5 years of age and younger. No deaths were reported; however, serious events requiring hospitalization such as nausea, vomiting, lethargy, tachycardia, decreased respiration, bradycardia, hypotension, hypertension, sedation, somnolence, mydriasis, stupor, hypothermia, drooling, and coma have occurred. Ingestion of only a small amount (1-2 mL; for reference, there are 5 mL in a teaspoon) of the eye drops or nasal spray can lead to serious adverse events in young children.

BACKGROUND: Most of these redness-relief eye drops and nasal decongestant sprays currently do not come packaged with child-resistant closures, so children can accidentally ingest the drug if the bottles are within easy reach. These products are sold under various brand names, as generics, and as store brands (see List of Products, included in the Drug Safety Communication, below).

RECOMMENDATION: Consumers should store these products out of reach of children at all times. If a child accidentally swallows OTC redness-relief eye drops or nasal decongestant spray, call your local poison control center immediately.