

Esophageal retention of loratadine plus pseudoephedrine extended-release tablets (Claritin-D 24 Hour)

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The following case report details an adverse event accompanying the ingestion of loratadine and pseudoephedrine USP extended-release tablets (Claritin-D 24-Hour tablets).

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CASE REPORT

A 56-year-old atopic white female with a 30-year history of asthma and rhinitis consulted her allergist on May 16, 1997 with complaints of severe nasal stuffiness for 2 two weeks. Previous skin prick tests had identified multiple pollen sensitivities. Past courses of immunotherapy on two occasions had resulted in marked improvement of all symptoms, but she discontinued this therapy in 1994. It was noted that her symptoms correlated closely with local seasonal peaks of hickory, walnut, and mulberry pollen, all of which had caused strong skin prick test responses. She had been maintained on therapy with inhaled beclomethasone and

salmeterol for her asthma, which did not flare with the occurrence of rhinitis.

Physical examination revealed a pale, boggy, and obstructed nasal mucosa. There was no visible mucopus and no tenderness overlying the sinuses. Her lungs were clear. The impression was recurrent allergic rhinitis caused by tree pollen sensitivity, with nasal congestion as the predominant symptom. A sample tablet of loratadine plus pseudoephedrine USP extended-release formulation (Claritin-D 24 Hour) was dispensed to her, along with a prescription for this drug.

On her way out of the office, the patient was observed to swallow the sample Claritin-D 24-Hour tablet with a small sip of iced cola. She immediately complained to staff that "the pill didn't go down." The patient was able to ingest small amounts of water, but this failed to dislodge the pill. A careful examination of the mouth and oral pharynx did not reveal retention of the medication at that level. After 30 minutes of further observation with no improvement, the patient was transported to a hospital emergency department. A gastroenterology consult was requested, and endoscopic removal of the tablet was contemplated. As an interim measure, 1 ml of glucagon was administered intramuscularly. The same dose of glucagon was administered intravenously after 30 additional minutes. Ten minutes later the patient vomited up approximately 150 ml of fluid plus the tablet, which appeared unaltered. It had been retained for more than 2 hours. The patient felt immediate relief and was discharged soon thereafter.

DISCUSSION

Schering-Plough, Inc., the manufacturer of Claritin-D 24-Hour tablets, was notified of this incident. They confirmed that 24 similar events have been reported to date during postmarketing experience with the drug. Patients ranged in age from 13 to 73 years, with a 60:40 female:male ratio. At present, the incidence of this side effect is 1 per 100,000 prescriptions (Cobert B, personal communication, 1997). Of these incidents, approximately half involved history of previous esophageal disorders. Our patient had no such history. The latest revision of the package insert dated May 1997 warns of the possibility of "mechanical gastrointestinal tract obstruction."¹ In addition to her use of salmeterol and beclomethasone, our patient had been taking trazodone and alprazolam for more than a year. A search of the Clinical Pharmacology Database for these drugs at Physicians' Online Network failed to identify any reports of esophageal dysfunction associated with their use.

Claritin-D 24-Hour tablets have an extended-release delivery system based on hydrophilic matrix technology.² The outer coat contains 10 mg of loratadine for immediate release. The core contains 240 mg of pseudoephedrine imbedded in a hydrophilic polymer matrix of hy-

droxypropyl methylcellulose. After reaching the stomach, the outer film dissolves to release loratadine. Next, gastrointestinal fluids slowly hydrate the polymer core, forming a gel layer from which pseudoephedrine slowly diffuses.

An informal experiment was carried out with Claritin-D 24-Hour tablets. When added to a medicine cup containing 15 ml of water, it was noted that the outer coat became immediately tacky. When the tablet was transferred to the mouth of the observer, it adhered to the roof of the mouth until additional water was taken to dislodge it. When removed from the water by hand, the tablet appeared slightly adhesive, a property that increased as it dried. According to a Schering-Plough official, this formulation is being reevaluated, and the constituent causing the stickiness has not been definitely identified (Basso L, personal communication, 1997).

Extended-release albuterol (Volmax, Muro Pharmaceuticals) was then tested and found to have a similarly tacky outer layer, but the tablet is so small that esophageal obstruction is unlikely. A similar experiment was carried out with extended-release theophylline (Uniphyll, Purdue Frederick). This tablet remained undissolved in 15 ml of water for more than 15 minutes, and the outer coat was not tacky. Finally, a clarithromycin 500 mg tablet (Biaxin, Abbot Laboratories) was tested. It was selected because it appeared larger than the loratadine formulation. On immersion in water, its outer coating became immediately tacky, but in less than 2 minutes the tablet decomposed into a suspension.

It seems likely that Claritin-D 24-Hour tablets pose a small but definite risk of esophageal obstruction in patients who have preexisting esophageal disorders or who fail to use sufficient amounts of fluid when ingesting the product. The mechanism of esophageal retention is uncertain but may involve tablet size or shape and/or the adhesive property of the outer loratadine-containing coat.

Some patients pride themselves on their ability to swallow pills without accompanying fluids. This practice should be explicitly discouraged by the prescribing physician when Claritin-D 24-Hour tablets are recommended.

REFERENCES

1. Claritin-D 24 Hour package insert. Kenilworth (NJ): Schering-Plough, Inc.; 1997.
2. Basso L. Document 1997-29853. Kenilworth (NJ): Schering Laboratories; 1997.