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Upper gastrointestinal obstruction associated with Claritin-D 24 Hour Extended Release tablets

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The licensing application for Claritin-D 24 Hour Extended Release tablets (Claritin-D 24 Hour) was approved by the Food and Drug Administration on August 23, 1996, for the treatment of antihistamine-responsive symptoms and congestion associated with seasonal allergic rhinitis. Each Claritin-D 24 Hour tablet contains 10 mg of loratadine in the tablet film coating for immediate release and 240 mg of pseudoephedrine sulfate in the core, which is released slowly, allowing for once-daily administration. Although the Claritin-D 24 Hour tablet is large (Fig. 1), there were no patient-reported problems with swallowing the pill or complaints of the tablet becoming lodged in the throat or esophagus in the clinical trials conducted in support of the safety and efficacy of the drug product. Shortly after approval, five reports of throat or esophageal obstruction were received by the Division of Pharmacovigilance and Epidemiology at the Food and Drug Administration. These case reports are summarized and discussed below.

CASE REPORTS

Patient 1

A 19-year-old woman with a history of asthma reported that the first dose of Claritin-D 24 Hour tablets became lodged in her throat. Paramedics were called, and the Heimlich maneuver was performed without success. After transport to a local emergency facility, she was seen by an ear, nose, and throat physician who sprayed her throat with a local anesthetic in preparation for direct laryngoscopy. The introduction of the instrument caused her to cough up the tablet, presumably as a result of induction of her gag reflex. The patient recovered without sequelae. Her medical history was unremarkable for upper gastrointestinal disease, and she had no history of difficulty swallowing tablets.

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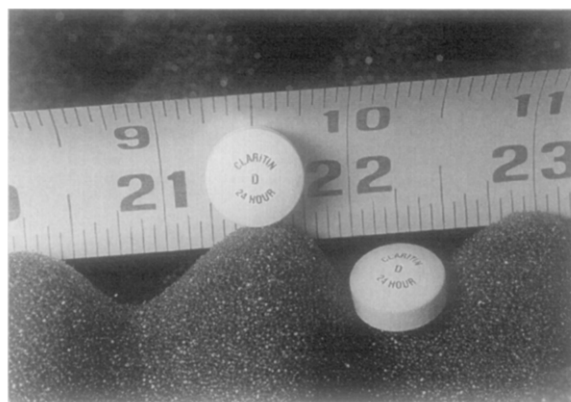


FIG. 1. Claritin-D 24 Hour Extended Release tablet (scale in inches).

Patient 2

A 37-year-old woman reported that the first dose of Claritin-D 24 Hour tablets became lodged in her throat and she was unable to swallow the tablet despite the fact that the tablet had been taken with a full 8-ounce glass of water. She was taken to the local emergency department, and an "esophageal sphincter obstruction" was diagnosed. Esophagoscopy was performed while the patient was under general anesthesia, and the tablet was removed from the cricopharyngeal area. The examining physician reported no anatomic deformity and believed that the "tablet size and coating caused an esophageal sphincter spasm." The patient recovered without sequelae.

Patient 3

A 67-year-old woman reported that the first dose of Claritin-D 24 Hour tablets became lodged in her throat, and she required transfer to a local emergency department. A barium swallow revealed complete esophageal obstruction requiring esophagoscopy while the patient was under general anesthesia. The tablet was removed, and the patient recovered without sequelae. A second direct visualization ruled out anatomic stricture. She had similar problems with large vitamin tablets in the past; however, she had never previously required mechanical removal of these tablets.

Patient 4

A 41-year-old woman with a history of difficulty swallowing large tablets had difficulty swallowing her first dose of Claritin-D 24 Hour tablets. The patient was transferred to an emergency department where conservative measures (i.e., administration of mineral oil and intravenous muscle relaxant) failed to dislodge the tablet. Esophagoscopy was performed, and a complete esophageal obstruction caused by the tablet was diagnosed. The tablet was pulverized, and the mechanical obstruction was relieved. A subsequent esophagoscopy revealed no anatomic problem with the patient's upper gastrointestinal tract. She had taken Claritin tablets and Claritin-D 12 Hour extended-release tablets previously without problems.

Patient 5

A 73-year-old woman with a history of difficulty swallowing tablets took her first dose of Claritin-D 24 Hour tablets with a full glass of water and felt the tablet get stuck in her throat. She drank more water but was unable to dislodge the tablet. She was taken to a local emergency department and was seen by a gastroenterologist who was unable to remove the tablet by flexible esophagoscopy. The physician reported that the tablet "adhered to the mucosal surface." A second esophagoscopy was performed while the patient was under general anesthesia, and

the tablet was removed in "piecemeal" fashion. An old esophageal stricture was detected.

DISCUSSION

Although these reports are relatively few in number, the similarity between them is striking. The tablet became lodged in the upper gastrointestinal tract after the first dose, requiring hospital transfer. In only one of these cases was a preexisting esophageal anatomic deformity detected. These cases indicate that there may be certain patients who will have trouble swallowing the Claritin-D 24 Hour Extended Release tablet. Although the size alone may play a role, the physicochemical properties of the tablet may contribute to the lodging phenomenon and account for some reported descriptions of the tablet adhering to mucosal surfaces. Until patient risk factors are more carefully identified, it may be reasonable to avoid prescribing this product for patients who have known upper gastrointestinal narrowing, abnormal esophageal peristalsis, or a history of difficulty swallowing tablets. Product labeling has been updated to inform prescribers of this adverse event associated with Claritin-D 24 Hour Extended Release tablets.

The effectiveness of Allerpet/c in reducing the cat allergen Fel d 1

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Investigating techniques to reduce allergen in cat dander is important because many patients who are specifically allergic live in houses with cats. Cat allergen is present in a range of particle sizes, the smaller of which can remain airborne for at least 3 hours and would be expected to enter the peripheral lung.^{1,2} De Blay et al.³ suggested that the combination of vacuum cleaning, air filtration, limiting upholstered furniture, and washing the cat could be an effective method of reducing airborne cat allergen. Recently, we have found that washing a cat reduced the amount of allergen becoming airborne but that this effect lasted less than a week

(unpublished data). An alternative method used by pet owners for reducing cat allergen is the commercially available product Allerpet/c (Allerpet Inc., New York, N.Y.). According to the container, this product "... cleanses the hair of dander and saliva, the antigens considered to be the prime cause of allergic reactions to cats." Previous investigations have presented opposing data on the effectiveness of this treatment. An abstract by Koren et al.⁴ stated that cat allergen in the settled dust from houses with cats was reduced by the use of Allerpet/c on the cat. Klucka et al.,⁵ however, reported no significant reduction in the major airborne cat allergen Fel d 1 after treatment with Allerpet/c.

This study was designed to answer two questions. How much allergen is removed by wiping the cat with Allerpet/c, and does this treatment decrease airborne allergen released by the cat?

METHODS

The amount of allergen removed by Allerpet/c was assessed with 10 cats. The cats were first combed with a fine-tooth comb to remove any loose hair. A disposable

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