



Practice sting Pieces breaking loose of inhalation capsules lead to concerns for the patient

This Practical Incentive was developed in collaboration with Netherlands Pharmacovigilance Centre Lareb.

Pieces sometimes break loose when puncturing inhalation capsules. Netherlands Pharmacovigilance Centre Lareb regularly receives reports from patients who are concerned about inhaling these pieces. Although inhaling of the pieces is harmless, it can lead to patients' mistrust in using an inhaler.

Notifications

Up to November 2022, Netherlands Pharmacovigilance Centre Lareb received twenty-three reports of pieces of an inhalation capsule breaking loose. The reports show that patients sometimes worry about inhaling capsule slivers. Several patients found these pieces in their throat or after coughing up. Nine patients thought the capsule was made of plastic. In one report, this is known to have resulted in wrong use of the inhaler and in 12 reports the patient stopped using the inhalator. The Cyclohaler® was used in 18 reports, the Zonda® inhaler (Tiotrus®) in three reports and the Handihaler® (Spiriva®) in two reports. The following quotes from reports illustrate the concerns of patients:

1. Quote: "The capsules break badly in the Cyclohaler®. They break and splinter, so that you sometimes also inhale pieces of the plastic. Seems like a dangerous thing to me."
2. Quote: "People are likely to regularly and deeply inhale small pieces of plastic that detach from the capsule. When I removed the capsule from the inhaler after piercing it and shook it empty on an earthenware dish, I discovered small bright green pieces of plastic. I check the powder and then inhale it from the saucer."

Analysis

Inhalation capsules are made of excipients that are harmless after inhalation or ingestion, such as gelatin or hypromellose. This is stated in the beclometasone product information for use with the Cyclohaler® (gelatin capsules) and Tiogiva®, an inhaler containing hypromellose capsules. In all cases, the patient can safely inhale the entire dose from the inhaler. The splinters of the capsules remain behind or end up in the mouth or pharynx [1]. The storage condition of inhalation capsules can affect the quality of the capsules. Package inserts for inhalers state that inhalation capsules should be kept in their original packaging. High humidity makes capsules turn sticky and softer faster. Cracks in the capsule are more likely to occur at low humidity [2].

Recommendations

For healthcare professionals providing inhalation instructions

- Instruct patients to keep the inhalation capsules dry and at room temperature in their packaging, otherwise the capsules may splinter.
- If necessary, explain that splinters of capsules remain in the mouth or throat after inhalation. The material of the capsules is safe after ingestion.

For authors of inhalation protocols

State in the inhalation protocols that it is harmless if pieces of the capsule are swallowed or inhaled.

Referrals

1. Buttini F, Quarta E, Allegrini C, Lavorini F. Understanding the Importance of Capsules in Dry Powder Inhalers. *Pharmaceutics*. 2021 Nov 16;13(11):1936.
2. Renswouw DC, Laarhoven AC, Haren MJ, Bouvy ML, Weda M. Storage instructions for inhalation capsules: consequences of incorrect storage and adherence in daily practice. *J Pharm Pract*. 2010;23(6):548-52.