Misadministration of capsules for inhalation

The Food & Drug Administration would like to alert healthcare providers to errors involving the inadvertent oral administration of Foradil Aerolizer and Spiriva HandiHaler capsules for inhalation. In total, the FDA has received 30 cases concerning the inadvertent oral administration of the Foradil Aerolizer product and two concerning the Spiriva HandiHaler product. Although most cases did not indicate an adverse event, one case report described difficulty breathing following oral ingestion, one reported hospitalization due to a chronic obstructive pulmonary disease (COPD) exacerbation, and there was one unrelated death.

The unintentional oral administration of the Foradil Aerolizer and Spiriva HandiHaler capsules stems from the fact that these capsules resemble those typically taken orally. Additionally, the capsules are supplied in unit-of-use packages that do not prominently display "NOT FOR ORAL USE." Swallowing the capsules for inhalation, rather than using the capsule via the appropriate inhalation device may lead to delayed onset of action, reduced efficacy, and inadequate drug delivery.

Foradil Aerolizer (formoterol fumarate inhalation powder) is a long-acting, selective beta-2 adrenoreceptor agonist manufactured by Novartis. Foradil Aerolizer was approved on Feb. 16, 2001, under NDA 20-831, for the scheduled, maintenance treatment of asthma and COPD, and for the prevention of exercise-induced bronchospasm on an as-needed basis. Spiriva HandiHaler (tiotropium bromide inhalation powder) is a long-acting anticholinergic agent manufactured by Boehringer Ingelheim. Spiriva HandiHaler was approved on Jan. 30, 2004, under NDA 21-395, for the scheduled, maintenance treatment of asthma and COPD.

Two risk factors for errors need to be taken into consideration by healthcare practitioners and consumers alike when prescribing, dispensing, or receiving Foradil Aerolizer or Spiriva HandiHaler. The first involves the current packaging, labels, and labeling of the products. The unit-dose labels do not prominently indicate that the product is for "INHALATION USE ONLY." The principal display panels of the labels appear crowded. This crowding obscures the warning. A more prominently displayed warning statement may help prevent misadministration.

Additionally, the size and shape of the capsules promote the swallowing, rather than inhalation, of the Foradil Aerolizer and Spiriva HandiHaler capsules. This confusion might be reduced if the capsule were adequately marked with one of the following, "FOR INHALATION USE ONLY," "FOR USE WITH INHALER ONLY," or "NOT FOR ORAL USE."

While the FDA is working with the manufacturer on labeling and packaging changes to minimize potential user error and maximize patient safety, we offer the following suggestions:

- Counsel healthcare providers who administer and dispense this product (pharmacists and physicians who sample it) on its proper use, including the correct route of administration and the potential for confusion with oral products.
- Counsel patients about the potential confusion and ways to avoid it.
- Advise healthcare providers to avoid dispensing the capsules for inhalation separately from the inhalation device.
- If the capsules for inhalation are dispensed separately as unit-dose capsules, advise healthcare providers and patients to affix a cautionary label or statement indicating "FOR INHALATION USE WITH SPECIAL INHALER ONLY."
- Advise patients who are using oral medications to store the capsules for inhalation together with the inhaler in a location where the capsules are unlikely to be confused with other oral medications.
- Circle or otherwise highlight the "FOR INHALATION USE ONLY" statement on the product package and container if possible.

by Tina Tezky, Pharm.D., and Carol Holquist, R.Ph.

Tina M. Tezky, Pharm.D., is a Safety Evaluator, and Carol Holquist is Director of the Division of Medication Errors and Technical Support (DMETS), Office of Drug Safety, at the Food & Drug Administration.

MEDWATCH

To report a problem with an FDA-regulated product, please call 1-800-FDA-1088.