

Capsules for Inhalation Mistaken as Oral Capsules

When prescribing, dispensing or administering Foradil (formoterol fumarate) aerolizer or Spiriva (tiotropium bromide) Handihaler, medical professionals should consider the distinct possibility that these medications may mistakenly be swallowed rather than inhaled through their accompanying devices.

Foradil is a long-acting beta-2 agonist used in the treatment of asthma and chronic obstructive pulmonary disease (COPD), and Spiriva is an anticholinergic bronchodilator used for COPD. Each medication is available as a dry powder within a capsule, and the capsules are packaged in blister cards. When used correctly, the capsule is removed from the blister card and placed into the inhaler device. In the device, the capsule is punctured to allow the medication to be dispersed into the lungs as the patient inhales through a mouthpiece. Because capsule dosage forms are usually associated with oral administration, Foradil and Spiriva have mistakenly been swallowed.

The Institute for Safe Medication Practices has received numerous reports describing situations where patients have received these medications by the ineffective oral route. Most of the reports have come from hospitals and long-term care facilities; however, some have involved community pharmacy patients.

Reporters have cited the following contributing factors:

1. *Order communication* – Prescriptions may be communicated ambiguously. For example, a prescription with the instructions “Foradil one capsule orally every 12 hours” was received and dispensed by a pharmacy with the above instructions. This led the patient to believe that the medication was to be swallowed.

A physician order for “Spiriva oral inhalation once daily” led a nurse to administer the dose orally because she saw the word “oral” as part of the order. Also, medication administration records (MARs) may list these medications along with other oral medications. Such instructions often begin with the phrase “1 capsule,” leading nurses to think it’s an oral medication.

2. *Education* – Practitioners who are unfamiliar with this dosage form and patients that do not receive education from their prescriber or pharmacist may mistakenly administer the medication orally.

3. *Storage* – These products may be stored along with other oral medications in patients’ homes or in medication drawers and automated dispensing cabinets in long-term care facilities. If the inhaler device is separated from the capsules, caregivers are likely to assume (due to the dosage form) that the capsules are to be swallowed.

4. *Packaging and labeling* – Packaging is similar to that of other oral unit-dose medications and blister labeling is inadequate to protect against oral use.

SAFE PRACTICE RECOMMENDATIONS: To prevent similar errors with these medications, consider the following:

- Products should be ordered and entered into computer systems as “Foradil Aerolizer” and “Spiriva HandiHaler” to better distinguish the medication when it prints out on a patient’s medication administration record or pharmacy label.
- Instructions for both patients and staff must clearly express the need for the medication to be inhaled. For example, “Inhale the contents of one capsule every 12 hours using Aerolizer.” Avoid using instructions that begin with “One capsule...” or include the word “oral,” which may be misinterpreted.

If a prescriber’s instructions are nonspecific (e.g., 1 capsule BID or use once daily) pharmacists should express the instructions in a manner that clearly states how the medication is to be used.

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- Shortcuts could be programmed into computer systems to ensure that these products are ordered and dispensed with the proper instructions. For example, if the word “Spiriva” is entered in the instructions field, the phrase “Inhale the contents of one capsule once daily using HandiHaler” would be printed.
- Auxiliary messages stating “FOR USE ONLY WITH INHALER. DO NOT SWALLOW CAPSULE” or “FOR INHALATION ONLY” should prominently print out on medication administration records. Similar auxiliary labels could be placed on boxes and blister labels to help differentiate these capsules from other oral medications that may be stored in the same place or store these separately from oral dosage forms.
- Patients, caregivers, and staff must be educated regarding the proper administration of these medications before they are dispensed or administered. Training kits containing an inhaler device, placebo capsules, and patient education materials are available from each manufacturer.
- Capsules should be stored in the box provided along with the inhaler device. Do not dispense the capsules separately. In long-term care facilities, put the patient’s name on the inhaler device to ensure that it is returned to the correct patient’s box of medication.
- The [FDA Public Health Advisory](#) and the [FDA Patient Safety News](#) video should be reviewed for information on the correct use of both products and shared with colleagues and patients.

These errors should serve as a reminder that health professionals need to be very clear in their verbal and written instructions to patients and colleagues when medications are prescribed, dispensed or administered.

Editor’s note: This is article about medication errors was submitted by the Institute for Safe Medication Practices (ISMP). If you would like to report a medication error, go to the ISMP [Web site](#) or call 1-800-23-ERROR to report directly to the ISMP Medication Errors Reporting Program. ISMP address: 200 Lakeside Drive, Suite 200, Horsham, PA 19044-2321. The institute’s general phone number is 215-947-7797.

Act 25 to Strengthen Consumer Protection

On July 17 **Governor Edward G. Rendell** signed Act 25 into law, which is a major legislative accomplishment for the Bureau for Professional and Occupational Affairs and its boards. This law amends Act 48 of 1993 by adding a provision raising the maximum fine the board imposes for violations of the licensing laws or regulations from \$1,000 to \$10,000, as well as authorizing the licensing boards to impose the costs of investigation. Furthermore, the act provides privilege protection to Department of State investigative files, as well as confidentiality requirements.

“BPOA has been working to pass this legislation since 2004,” **Commissioner Basil L. Merenda** said.

“This is an important law because the new maximum fine acts as a very strong deterrent to unlawful activity by licensees, which in turn will enable us to more effectively protect the health, safety and welfare of every consumer in the commonwealth.”

Act 25 will affect all 29 boards where professionals range from physicians and cosmetologists to accountants and funeral directors. The law, which was passed in the legislature as Senate Bill 142, will go into effect 60 days after its enactment. At that time, prosecutors will be able to recommend to the respective licensing board to impose the maximum fine if the violation is egregious.

Mobilizing board members to reach across party lines to contact senators and representatives was also key in the enactment of this bill. The board members explained, from their viewpoint, why this legislation needed to be passed to effectively carry out Bureau of Professional and Occupational Affairs and each board’s mission.

Future plans for legislation includes proposals to create a statutory obligation for a licensee to cooperate with investigators and prosecutors in disciplinary matters and authorizing the boards’ authority to expunge a disciplinary history of a license for minor violations such as failure to complete the continuing education requirement.

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