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Oral Administration of Capsules for Inhalation

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*For U.S. subscribers, please select this link to Detail Document 210303, and for Canadian subscribers, this link to Detail Document 210315, for our patient handout, Tips for Correct Use of Metered Dose Inhalers (MDIs)*

**Background**

Both **Foradil Aerolizer** (formoterol fumarate inhalation powder), a long-acting, selective beta-2 adrenergic agonist, and **Spiriva HandiHaler** (tiotropium bromide inhalation powder), a long-acting anticholinergic bronchodilator, are supplied as powder in a capsule-loaded dosage form. In Canada, **Intal Spincaps** (sodium cromoglycate), a mast cell stabilizer, is also supplied in a capsular form. These capsules are intended only for loading into the brand name dry-inhalation device. Because these capsules look like capsules for oral administration, accidental oral administration can occur.

**Commentary**

The FDA has received reports of misadministration of these capsules. Thirty cases of oral administration of **Foradil** inhalation capsules and two cases of oral administration of **Spiriva** inhalation capsules have been reported. Though very few of these reports indicated adverse outcomes, inappropriate administration obviously results in decreased therapeutic outcomes. One case reported difficulty in breathing and in another case the patient required hospitalization due to exacerbation of chronic obstructive pulmonary disease. Oral administration of these capsules resulted because the packaging and labeling did not readily display “not for oral use” warnings.

Manufacturers are currently revising package and product labels to assure safe and appropriate administration. It is not known when these products with revised labeling will reach pharmacies.

Whenever the inhalation capsules are separated from the inhalation device, the potential for oral administration is increased. Healthcare professionals should affix supplemental warning labels to capsules whenever the inhalation capsules are separated from devices. Patients should be counseled to store the capsules with the inhalers to avoid confusion and they should be shown how to correctly load the capsules and use the inhaler.

Report any cases of misadministration. In the US, call the FDA MEDWATCH program at 1-800-FDA-1088. The MEDWATCH program is also available on-line at www.fda.gov/medwatch. Or report to the USP Medication Errors Reporting Program in cooperation with the Institute for Safe Medication Practices at 1-800-23-ERROR or at www.usp.org/patientSafety/reporting/mer.html. In Canada, call the Canadian Adverse Drug Reaction Monitoring Program at 1-866-234-2345. The Canadian adverse reaction reporting form can be found at http://www.hc-sc.gc.ca/hpb-dgpsa/tpd-dpt/adverse_e.pdf. It should be completed and faxed to 1-866-678-6789. You can also contact the Institute for Safe Medication Practices (ISMP) by calling 215-947-7797 or reporting on-line at www.ismp.org/Pages/communications.asp.

**Sound-Alike, Look-Alike Concern**

Recently, a sound-alike, look-alike **Spiriva-Inspira** concern was reported to the Institute for Safe Medication Practices (ISMP). In the reported case, **Spiriva** 25 mg orally daily was ordered. A pharmacist intercepted the order due to the oral route of administration and clarified the order to **Inspira** 25 mg orally daily.
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References

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