

**From:** MannKind Corporation  
**To:** Professional Societies  
**Subject:** Risk of acute bronchospasm with AFREZZA in patients with chronic lung disease

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## AFREZZA<sup>®</sup> REMS

### FDA Required REMS Safety Information

- **Risk of acute bronchospasm in patients with chronic lung disease**
    - Acute Bronchospasm has been observed in patients with asthma and COPD using AFREZZA
  - **Contraindicated in patients with chronic lung disease such as asthma or COPD**
  - **Need to evaluate all patients for lung disease before starting AFREZZA**
- Before initiating AFREZZA, perform**
- a detailed medical history
  - physical examination, and
  - spirometry (FEV1)

### Important Safety Notice

The FDA has required MannKind Corporation to distribute this safety notice to your organization as part of their AFREZZA REMS (Risk Evaluation and Mitigation Strategy) program. We request that you inform you members about the following **serious risks of AFREZZA:**



- **Risk of acute bronchospasm in patients with chronic lung disease**
- **Contraindicated in patients with chronic lung disease as asthma or COPD**
- **Need to evaluate patients for lung disease before starting AFREZZA**

A non-promotional factsheet, reviewed by the FDA, with more detailed safety information on these risks, and a link to the Prescribing Information including the BOXED WARNING are available at [www.AfrezzaREMS.com](http://www.AfrezzaREMS.com).

**Indication**

AFREZZA (insulin human) Inhalation Powder is a rapid acting inhaled insulin indicated to improve glycemic control in adult patients with diabetes mellitus.

**Important limitations of use**

- Not a substitute for long-acting insulin. In patients with type1 diabetes, must use with a long-acting insulin
- Not recommended for the treatment of diabetic ketoacidosis
- Not recommended in patients who smoke or have recently stopped smoking

This email does not contain the complete safety profile of AFREZZA. To review the Prescribing Information and Medication Guide, see links below:

[Prescribing information](#)

[Medication Guide](#)

Please visit [www.AfrezzaREMS.com](http://www.AfrezzaREMS.com) for more information.

**Reporting Adverse Events**

You are encouraged to report negative side effects of prescription drugs to MannKind Corporation at 1-877-323-8505 and/or the FDA [www.fda.gov/medwatch](http://www.fda.gov/medwatch), or call 1-800-FDA-1088.

Signature,



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