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## AFREZZA REMS (Risk Evaluation and Mitigation Strategy)

### What is the AFREZZA REMS?

A REMS (Risk Evaluation and Mitigation Strategy) is a program required by the Food and Drug Administration (FDA) to manage known or potential serious risks associated with a drug product.

The purpose of the AFREZZA REMS is to inform healthcare providers about the following risks of AFREZZA:

- Risk of acute bronchospasm in patients with chronic lung disease
- 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 (FEV<sub>1</sub>)

A non-promotional factsheet, reviewed by the FDA, with more detailed safety information on these risks is available in the box to the right.

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

### Materials for Healthcare Provider



[AFREZZA REMS Safety Information for Providers Factsheet](#)



[REMS Letter to Healthcare Providers](#)

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