AFREZZA® (insulin human) Inhalation Powder
REMS (Risk Evaluation and Mitigation Strategy)

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)

Risk of Acute Bronchospasm in Patients with Chronic Lung Disease

- Counsel patients to inform their HCP if they have a history of lung disease
- Do not use in patients with chronic lung disease

Appropriate Patient Selection

AFREZZA is contraindicated in patients with chronic lung disease such as asthma or chronic obstructive pulmonary disease (COPD)

Patient Evaluation Before Initiating Therapy

- Before initiating, perform a detailed medical history, physical examination, and spirometry (FEV1) in all patients, to identify potential underlying lung disease

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 type 1 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

BOXED WARNING- Risk of Acute Bronchospasm in Patients with Chronic Lung Disease

- Acute bronchospasm has been observed in patients with asthma and COPD using AFREZZA
- AFREZZA is contraindicated in patients with chronic lung disease such as asthma or COPD.
- Before initiating AFREZZA, perform a detailed medical history, physical examination, and spirometry (FEV1) to identify potential lung disease in all patients

*What is the AFREZZA REMS?

A REMS (Risk Evaluation and Mitigation Strategy) is a program required by the FDA to manage known or potential serious risks associated with a drug product. FDA has determined that a REMS is necessary to ensure that the benefits of AFREZZA outweigh the risks of acute bronchospasm in patients. This factsheet is required by the FDA as part of the AFREZZA REMS program. Please visit www.AfrezzaREMS.com for further information.

Reporting Adverse Events:

To report adverse events contact:

- MannKind Corporation at 1-877-323-8505 and/or
- FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

This factsheet does not contain the complete safety profile for AFREZZA. Please refer to the Prescribing Information, including Boxed Warning, for further information.

MannKind Corporation