

# AFREZZA<sup>®</sup> (insulin human [rDNA origin]) Inhalation Powder

## A Novel Approach for Mealtime Glucose Control in Diabetes

**What is AFREZZA?** AFREZZA<sup>®</sup> (pronounced uh-FREZZ-uh) is a novel, ultra rapid-acting mealtime insulin therapy in late stage clinical investigation for the treatment of adult patients with Type 1 and Type 2 diabetes mellitus for the control of hyperglycemia. It is a drug-device combination product, consisting of AFREZZA Inhalation Powder pre-metered into single use dose cartridges and the light, discreet and easy-to-use AFREZZA Inhaler.

**How does it work?** AFREZZA has a unique pharmacokinetic profile that mimics the early phase release of mealtime insulin observed in healthy individuals. Administered at the start of a meal, AFREZZA dissolves in the lung immediately upon inhalation and delivers insulin quickly to the blood stream. Peak insulin levels are achieved within 12 to 14 minutes of administration.

**What have the AFREZZA clinical studies shown?** The AFREZZA clinical program involved 50 different studies of AFREZZA and over 5,000 adult patients. In clinical trials to date, AFREZZA has shown:

- A significant reduction in post-meal glucose fluctuations, which are believed to be an important risk factor in the development of complications
- The ability to achieve comparable levels of overall glucose control compared with present "state-of-the-art" treatment
- A lower risk of hypoglycemia, which is considered to be a major problem for patients
- Less weight gain than is typically associated with other insulin treatments

In a two-year pulmonary safety study in Type 1 and Type 2 adult diabetes patients, the changes in pulmonary function tests associated with AFREZZA were comparable to the changes seen in patients treated using usual care, consisting of insulin or oral therapies. The most common adverse events reported during AFREZZA clinical trials were hypoglycemia and mild, transient, non-productive cough.

**Why AFREZZA?** We believe that AFREZZA is able to satisfy diabetes patients' needs by being highly synchronized with the normal digestion of a typical meal. We believe that because of its unique pharmacokinetic profile, AFREZZA may be a promising new therapy for patients with Type 1 and Type 2 diabetes, as it controls post meal-time glucose levels with less weight gain and lower risk of hypoglycemia.