



Afrezza[®] (insulin human) Inhalation Powder Fact Sheet

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About Afrezza[®]

Afrezza[®] (insulin human) Inhalation Powder is the only inhaled insulin used to control high blood sugar in adults with type 1 and type 2 diabetes. Prescription Afrezza[®] (pronounced uh-FREZZ-uh) received approval from the U.S. Food and Drug Administration (FDA) on June 27, 2014.

Key Features of Afrezza[®]

- Inhaled insulin administration: Afrezza[®] is a drug-device combination product that consists of a dry formulation of human insulin delivered in a small and portable inhaler. Administered at the beginning of a meal, Afrezza[®] gets insulin into the body right when it is needed and works quickly to achieve blood sugar control. Peak insulin levels are achieved within 12 to 15 minutes.
- An alternate approach to mealtime blood sugar control: Afrezza[®] can help adult patients with diabetes control their blood sugar. The inhaler and cartridge can fit in a patient's hand. The inhaler does not require cleaning or maintenance.

Dosage and Administration of Afrezza[®]

- Afrezza[®] is available in 4-unit and 8-unit single-use cartridges that can be combined to achieve target blood sugar levels. The disposable inhaler can be used to take both 4-unit and 8-unit cartridges for up to 15 days.
- Afrezza[®] is inhaled by the patient at the beginning of a meal, using a single inhalation per cartridge. Patients should check with their healthcare professional as dosing must be individualized.

INDICATION

Prescription Afrezza is a rapid acting inhaled insulin used to treat adults with type 1 and type 2 diabetes for the control of high blood sugar.

LIMITATIONS OF USE

Do not use Afrezza as a substitute for long-acting insulin; Afrezza must be used in combination with long-acting insulin in patients with type 1 diabetes.

Do not use Afrezza to treat diabetic ketoacidosis.

Afrezza is not recommended in patients who smoke or who have recently stopped smoking.

IMPORTANT SAFETY INFORMATION FOR AFREZZA

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.

Please see additional Important Safety Information for Afrezza[®] on the following page and full Prescribing Information, including Boxed WARNING, at <http://products.sanofi.us/Afrezza/Afrezza.pdf>.

IMPORTANT SAFETY INFORMATION FOR AFREZZA (continued)

Do not use Afrezza if you have problems with your lungs, such as asthma or COPD. Do not use Afrezza during a low blood sugar reaction (hypoglycemia). If you are allergic to any of the ingredients in Afrezza, do not use Afrezza as this may cause a significant and severe allergic reaction.

Before using Afrezza, your doctor will take a medical history, and do a physical exam and a breathing test (called spirometry) to determine if you have lung problems. Patients with lung problems should not use Afrezza. If your doctor finds you have lung problems, use of Afrezza may cause a severe asthma-like breathing problem. Afrezza can reduce lung function, so your doctor will also want to test your breathing 6 months after starting Afrezza, and then each year after that, with more frequent testing done if you have symptoms such as wheezing or coughing. Tell your doctor if you currently have lung cancer or have had it in the past, or if you have an increased risk of developing lung cancer.

You must test your blood sugar levels while using insulin, such as Afrezza. Do not make any changes to your dose or type of insulin without talking to your healthcare provider. Any change of insulin should be made carefully and only under your doctor's care.

The most common side effect of insulin, including Afrezza, is low blood sugar (hypoglycemia), which can be serious and life-threatening. Some people may experience symptoms such as shaking, sweating, fast heartbeat, and blurred vision. It may cause harm to your heart or brain. It is important for you to understand how to manage the use of Afrezza, and to understand how to lessen the risk of hypoglycemia events.

Tell your doctor about other medicines you take, especially ones commonly called TZDs (thiazolidinediones) and supplements, because they can change the way insulin works. If you have heart failure or other heart problems, it may get worse while you take TZDs with Afrezza. Before starting Afrezza, it is important to tell your doctor about all your medical conditions including if you have a history of lung problems, if you are pregnant or plan to become pregnant, or if you are breast feeding or planning to breast-feed.

In addition to low blood sugar (hypoglycemia), other possible side effects associated with Afrezza include cough, throat pain or irritation, headache, diarrhea, tiredness, and nausea.

Please see full Prescribing Information for Afrezza[®], including Boxed WARNING, at <http://products.sanofi.us/Afrezza/Afrezza.pdf>.

Afrezza[®] is a registered trademark of MannKind Corporation.

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