

# FDA Approves New DPP-IV Inhibitor: Tradjenta (Linagliptin)

This article originally posted 03 May, 2011 and appeared in [Medication, Type 2 Diabetes, Issue 572](#)  
[Diabetes in control](#)

**A new prescription medication Tradjenta (linagliptin) has gained FDA approval for the treatment of adult Type 2 diabetes. Tradjenta will compete with two other drugs in the same family, Onglyza and Januvia....**

It is the first DPP-4 inhibitor approved at one dosage strength: no dose adjustment is recommended for patients with Type 2 diabetes who have kidney or liver impairment.

Boehringer Ingelheim Pharmaceuticals, Inc. and Eli Lilly and Company today announced that the U.S. Food and Drug Administration (FDA) has approved Tradjenta™ (linagliptin) tablets, a prescription medication used along with diet and exercise to lower blood sugar in adults with Type 2 diabetes. Tradjenta can be used as monotherapy or in combination with other commonly prescribed medications for Type 2 diabetes -- metformin, sulfonylurea or pioglitazone -- and demonstrated reductions in hemoglobin A1c levels up to 0.7 percent (compared to placebo).

Tradjenta should not be used in patients with Type 1 diabetes or for the treatment of diabetic ketoacidosis (increased ketones in the blood or urine). It has not been studied in combination with insulin.

Tradjenta belongs to a class of prescription medications called dipeptidyl peptidase-4 (DPP-4) inhibitors and is the first member of its class to be approved at one dosage strength (5 mg, once daily). With Tradjenta, no dose adjustment is recommended for patients with kidney or liver impairment. Tradjenta is a tablet that can be taken with or without food. Tradjenta lowers blood sugar in a glucose dependent manner by increasing incretin levels, which increase insulin levels after meals and throughout the day.

Tradjenta 5 mg once daily was approved based on a clinical trial program which included approximately 4,000 adults with Type 2 diabetes. Included in the program were placebo-controlled studies evaluating Tradjenta as monotherapy and in combination with the commonly prescribed medications for Type 2 diabetes.

When used in combination with metformin, sulfonylurea, and metformin plus sulfonylurea, the addition of Tradjenta resulted in significant A1c reductions of 0.6, 0.5, and 0.6 percent respectively (compared to placebo). In the initial combination of Tradjenta plus pioglitazone, significant reductions in A1c of 0.5 percent were observed compared to placebo.

*Diabetes, Obesity & Metabolism (Feb 2011)*