



Januvia[®] (sitagliptin), Janumet[®], Janumet XR (sitagliptin/metformin), Jentadueto[®], Jentadueto XR (linagliptin/metformin), Tradjenta[®] (linagliptin), Glyxambi[®] (linagliptin/empagliflozin) – New warning

- On August 10, 2017, the FDA approved updates to the *Warnings and Precautions* sections of the [Januvia \(sitagliptin\)](#), [Janumet \(sitagliptin/metformin\)](#), [Janumet XR \(sitagliptin/metformin XR\)](#), [Jentadueto \(linagliptin/metformin\)](#), [Jentadueto XR \(linagliptin/metformin XR\)](#), [Tradjenta \(linagliptin\)](#), and [Glyxambi \(linagliptin/empagliflozin\)](#) drug labels regarding heart failure.
- Januvia, Janumet, Janumet XR, Jentadueto, Jentadueto XR, Tradjenta, and Glyxambi are approved as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus (T2DM).
 - Combination products are indicated when treatment with both agents is appropriate.
 - These products should not be used in patients with type 1 diabetes or for the treatment of diabetic ketoacidosis.
 - These products have not been studied in patients with a history of pancreatitis.
 - [Jardiance[®] \(empagliflozin\)](#) is indicated to reduce the risk of cardiovascular (CV) death in adults with T2DM and established CV disease. However, the effectiveness of Glyxambi on reducing the risk of CV death in adults with T2DM and CV disease has not been established.
- An association between dipeptidyl peptidase-4 (DPP-4) inhibitor treatment and heart failure has been observed in CV outcomes trials for two other members ([Nesina[®] \[alogliptin\]](#) and [Onglyza[®] \[saxagliptin\]](#)) of the DPP-4 inhibitor class. These trials evaluated patients with T2DM and atherosclerotic CV disease.
- The risks and benefits of Januvia, Janumet, Janumet XR, Jentadueto, Jentadueto XR, Tradjenta, and Glyxambi should be considered prior to initiating treatment in patients at risk for heart failure, such as those with a prior history of heart failure and a history of renal impairment, and observe these patients for signs and symptoms of heart failure during therapy.
- Patients should be advised of the characteristic symptoms of heart failure and to immediately report such symptoms. If heart failure develops, evaluate and manage according to current standards of care and consider discontinuation of Januvia, Janumet, Janumet XR, Jentadueto, Jentadueto XR, Tradjenta, or Glyxambi.
- Products containing metformin (Janumet, Janumet XR, Jentadueto, and Jentadeuto XR) carry a boxed warning for lactic acidosis.



OptumRx[®] specializes in the delivery, clinical management and affordability of prescription medications and consumer health products. We are an Optum[®] company — a leading provider of integrated health services. Learn more at [optum.com](#).

All Optum[®] trademarks and logos are owned by Optum, Inc. All other brand or product names are trademarks or registered marks of their respective owners.

This document contains information that is considered proprietary to OptumRx and should not be reproduced without the express written consent of OptumRx.

RxNews[®] is published by the OptumRx Clinical Services Department.

©2017 Optum, Inc. All rights reserved.