

Linagliptin-containing products (Glyxambi®, Jentadueto®, Jentadueto XR®, Tradjenta®) – New Warning

- On December 23, 2016, the FDA approved a new update to the *Warnings and Precautions* section of the Glyxambi (empagliflozin/linagliptin), Jentadueto (linagliptin/metformin), Jentadueto XR (linagliptin/metformin extended-release), and Tradjenta (linagliptin) drug labels regarding bullous pemphigoid.
- Tradjenta is a dipeptidyl peptidase-4 (DPP-4) inhibitor indicated as an adjunct to diet and exercise to improve glycemic control in adults with T2DM.
- Jentadueto and Jentadueto XR are DPP-4 inhibitors and biguanide combination products indicated as an adjunct to diet and exercise to improve glycemic control in adults with T2DM when treatment with both linagliptin and metformin is appropriate.
- Glyxambi is a DPP-4 inhibitor and a sodium-glucose co-transporter 2 (SGLT-2) combination product indicated as an adjunct to diet and exercise to improve glycemic control in adults with T2DM when treatment with both linagliptin and Jardiance is appropriate.
- Tradjenta, Jentadueto, Jentadueto XR, and Glyxambi are not for treatment of type 1 diabetes or diabetic ketoacidosis.
- Tradjenta, Jentadueto, Jentadueto XR, and Glyxambi have not been studied in patients with a history of pancreatitis. It is unknown whether patients with a history of pancreatitis are at an increased risk for the development of pancreatitis while using Glyxambi.
- Postmarketing cases of bullous pemphigoid requiring hospitalization have been reported with DPP-4 inhibitor use.
 - In reported cases, patients typically recovered with topical or systemic immunosuppressive treatment and discontinuation of the DPP-4 inhibitor.
 - Patients should report development of blisters or erosions while receiving Tradjenta, Jentadueto, Jentadueto XR, or Glyxambi.
 - If bullous pemphigoid is suspected, Tradjenta, Jentadueto, Jentadueto XR, or Glyxambi should be discontinued and referral to a dermatologist should be considered for diagnosis and appropriate treatment.
- Other warnings and precautions of Tradjenta, Jentadueto, Jentadueto XR, and Glyxambi include pancreatitis, use with medications known to cause hypoglycemia, hypersensitivity reactions, severe and disabling arthralgia, and macrovascular outcomes.
 - Like other metformin-containing products, Jentadueto and Jentadueto XR also carry a warning and precaution for vitamin B₁₂ levels.
 - Like other SGLT-2-containing products, Glyxambi also carries warnings and precautions for hypotension, ketoacidosis, impairment in renal function, urosepsis and pyelonephritis, genital mycotic infections, and increased low-density lipoprotein cholesterol.

- Like other metformin-containing products, Jentaduetto and Jentaduetto XR carry a boxed warning for lactic acidosis.



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