

Alogliptin-containing products (Nesina®, Oseni®, Kazano®) – New Warning

- On December 12, 2016, the <u>FDA approved</u> a new update to the <u>Warnings and Precautions</u> section of the <u>Nesina (alogliptin)</u>, <u>Kazano (alogliptin/metformin)</u>, and <u>Oseni (alogliptin/ pioglitazone)</u> drug labels regarding bullous pemphigoid.
- Nesina is a dipeptidyl peptidase-4 (DPP-4) inhibitor indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus (T2DM).
- Kazano is a DPP-4 inhibitor and a biguanide combination product indicated as an adjunct to diet and
 exercise to improve glycemic control in adults with T2DM when treatment with both alogliptin and
 metformin is appropriate.
- Oseni is a DPP-4 inhibitor and a thiazolidinedione combination product indicated as an adjunct to diet and
 exercise to improve glycemic control in adults with T2DM when treatment with both alogliptin and
 pioglitazone is appropriate.
- Nesina, Kazano, and Oseni are not for treatment of type 1 diabetes or diabetic ketoacidosis.
- 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 Nesina, Kazano, or Oseni.
 - If bullous pemphigoid is suspected, Nesina, Kazano, or Oseni should be discontinued and referral
 to a dermatologist should be considered for diagnosis and appropriate treatment.
- Other warnings and precautions of Nesina, Kazano, and Oseni include pancreatitis, heart failure, hypersensitivity reactions, hepatic effects, use with medications known to cause hypoglycemia, severe and disabling arthralgia, and macrovascular outcomes.
 - Like other metformin-containing products, Kazano also carries a warning and precaution for vitamin B₁₂ levels.
 - Like other pioglitazone-containing products, Oseni also carries warnings and precautions for edema, fractures, bladder cancer and macular edema.
- Like other metformin-containing products, Kazano carries a boxed warning for lactic acidosis.
- Like other pioglitazone-containing products, Oseni carries a boxed warning for congestive heart failure.



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