

FDA Warns of Potential Worsening of Macula Edema in Diabetics Taking Avandia and Avandamet

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The FDA and pharmaceutical giant GlaxoSmithKline (GSK) are warning medical professionals about reports of new or worsening diabetic eye complications in diabetics taking Avandamet or Avandia.

The eye complication, known as macula edema, is a result of fragile and leaking blood vessels in the eye. The condition affects the part of the eye where sharp, straight-ahead vision occurs, and therefore can lead to blurry vision.

Patients should immediately alert their doctor if they notice any change in their vision such as blurriness, decreased color sensitivity, or the ability to see in the dark.

Avandia and Avandamet are made by GSK to treat Type 2 diabetes. Both drugs contain the drug rosiglitazone. Avandamet also contains a second drug called metformin.

A GlaxoSmithKline letter sent to doctors makes these points:

- * The reports are "very rare."
- * Most patients also reported swelling in their legs and feet (peripheral edema) at the same time.
- * In some cases the macula edema stopped or improved when patients stopped taking the drugs.
- * In one case, macula edema stopped when the drug's dose was reduced.

Over 5 million people worldwide have taken Avandia and 769,000 have taken Avandamet.

Diabetes can cause swelling, including swelling or edema in the back of the eyes. One complication of long-term diabetes is that the layer contains blood vessels that can become fragile or damaged.

Macula edema also can be related to high blood pressure, abnormal cholesterol levels, or poor control of blood sugar.

Regardless of any drug they take, individuals with diabetes should get eye exams at least once a year from an ophthalmologist.