

Rosiglitazone: End of the road



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The European Medicines Agency (EMA) has recommended the Europe-wide suspension of the marketing authorisations for all rosiglitazone formulations (Avandia® and Avandamet® in the UK). These medicines will stop being available in Europe within the next few months (EMA, 2010).

Rosiglitazone, the first thiazolidinedione (TZD) to come to market, has been shrouded in controversy since its launch in 2000. As a new class of drug, rosiglitazone (GlaxoSmithKline [GSK], Uxbridge) claimed to reduce peripheral insulin resistance, leading to a reduction in blood-glucose concentration. However, 7 years later Nissen and Wolski (2007) raised concerns about the cardiovascular (CV) safety of rosiglitazone.

At the American Diabetes Association's 70th Scientific Sessions in Orlando this year there were rumblings of the rosiglitazone licence being revoked by the US Food and Drug Administration. Some 3 months later, at the European Association for the Study of Diabetes conference in Stockholm, an announcement was made by the EMA that, following a complete review of the benefit–risk profile of products containing rosiglitazone (Avandia®, Avandamet® and Avaglim®) with focus on CV safety, the EMA's Committee for Medicinal Products for Human Use concluded that “the benefits of rosiglitazone no longer outweigh its risks and recommended the suspension of the marketing authorisation of the medicines” (EMA, 2010).

On the same day, GSK released a statement outlining that “patient safety is paramount”, recommending that:

- Prescribers are advised not to issue any new or repeat prescriptions of rosiglitazone-containing medicines.
- Prescribers are advised to review currently treated patients and switch them to suitable alternative treatment.
- Pharmacists are advised to refer patients to their doctor for advice on their treatment.
- Patients are advised to make an appointment to discuss their treatment and not to stop taking rosiglitazone without consulting their doctor.

This information has been echoed in position statements from a range of organisations, and specific advice on alternative regimens for individuals currently taking rosiglitazone has been given by the Primary Care Diabetes Society (available at: <http://bit.ly/doama1>).

How this situation may affect the other TZD, pioglitazone, is not known, although some prescribers may believe that there is a possibility of a “class” effect regarding CV risk. However, it should be noted that evidence to explain the different CV risk profiles of rosiglitazone and pioglitazone, in spite of belonging to the same drug class, has now emerged (Rosen, 2010). In addition, evidence suggests that pioglitazone either confers no increased CV risk or, in some circumstances, protects against myocardial infarction (Graham et al, 2010).

It is essential that we avoid a knee-jerk reaction. We must treat everyone as an individual and agree, with the person with diabetes, an appropriate treatment regimen for their needs.

New global injection recommendations

On a different note, this September saw the launch of new global injection recommendations for people with diabetes (Frid et al, 2010). These are a result of various meetings within Europe to use the most up-to-date scientific evidence and consensus on best practice in injection technique.

On 4 June 2010 a group of experienced DSNs met in London to explore these recommendations and convert them into a UK version. This meeting was facilitated by the FIT (Forum for Injection Technique) board. As you will see, your own copy of the first UK injection technique recommendations has been included as a supplement to this edition of *JDN*.

I do hope you will read this document and implement its recommendations. For any injectable therapy to work optimally, it must be injected using the correct technique, in the correct site, every time. I believe that it is up to us, the healthcare professionals, to ensure we are up to date so we can pass on this information to people with diabetes who need injectable therapy. ■

European Medicines Agency (2010) *European Medicines Agency recommends suspension of Avandia, Avandamet and Avaglim*. EMA, London. Available at: <http://bit.ly/cjiXfU> (accessed 06.10.10)

Frid A, Hirsch L, Gasper R et al (2010) New injection recommendations for patients with diabetes. *Diabetes Metab* 36(Suppl): S4–16

Graham DJ, Ouellet-Hellstrom R, MaCurdy TE et al (2010) Risk of acute myocardial infarction, stroke, heart failure, and death in elderly Medicare patients treated with rosiglitazone or pioglitazone. *JAMA* 304: 411–18

Nissen SE, Wolski K (2007) Effect of rosiglitazone on the risk of myocardial infarction and death from cardiovascular causes. *N Engl J Med* 356: 2457–71

Rosen CJ (2010) Revisiting the rosiglitazone story – lessons learned. *N Engl J Med* 363: 803–6

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