



MEDSAFE

**NEW ZEALAND MEDICINES
AND MEDICAL DEVICES
SAFETY AUTHORITY**

A BUSINESS UNIT OF
THE MINISTRY OF HEALTH

www.medsafe.govt.nz

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Dear Healthcare Professional

Suspension of rosiglitazone-containing medicines: Avandia.

Medsafe and MARC advise:

- Avandia will be suspended in New Zealand from **Friday 29 April 2011**.
- This action is due to increased risk of myocardial infarction associated with rosiglitazone treatment.
- Do not start any new patients on Avandia and review the treatment of any patients currently taking this medicine.

In December 2010 the Medicines Adverse Reactions Committee (MARC) and Medsafe conducted a statutory review of the benefits and risks of treatment with rosiglitazone-containing medicines.¹ This followed regulatory action in Europe suspending rosiglitazone-containing medicines and to impose significant restrictions on use in the U.S.

The potential of rosiglitazone to cause myocardial infarction was of primary concern in the MARC review. The MARC considered that data from meta-analyses and observational studies were consistent with an increased risk of myocardial infarction in patients treated with rosiglitazone. The same risk was not seen for pioglitazone. Conversely, a randomised (but open-label) clinical study investigating cardiovascular safety of rosiglitazone (RECORD study) did not show any such association. Overall the MARC considered that the balance of benefits and risks for rosiglitazone was unfavourable.

In view of the conflicting data, the MARC recommended that the most appropriate action was suspension of the consents to distribute rosiglitazone containing medicines in New Zealand, until such time as satisfactory evidence can be provided by the company to identify a population of patients for whom the benefits of rosiglitazone treatment outweigh the risks.

¹ An overview of the data considered is published on the Medsafe website in association with the December MARC meeting minute.

Minutes from MARC meetings can be found at: <http://www.medsafe.govt.nz/profs/adverse.asp>

Data sheets can be found at <http://www.medsafe.govt.nz/profs/Datasheet/dsform.asp>

To allow a period of time for patients to initiate alternative treatment the MARC recommended a delay to the suspension coming into effect. Thus the date for suspension of Avandia is **29 April 2011**. After this date Avandia can only be legally supplied in New Zealand under the provisions in the Medicines Act 1981 that relate to the supply of unapproved medicines.

Medsafe advises that although pioglitazone may be the most obvious alternative treatment, this may not be appropriate for patients who are at high risk of heart failure or fracture. When selecting alternative treatments consideration should be given to recommended combinations, contraindications, cautions and side effects (as outlined in the data sheets) as well as patient preference. If pioglitazone is the alternative treatment of choice, please note that 30 mg of pioglitazone is roughly equivalent to 4 mg of rosiglitazone in terms of HbA1c reduction.

Yours sincerely

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