

Safeguarding public health
Defective Medicines Report Centre
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MHRA

DRUG ALERT

CLASS 3 MEDICINES RECALL

Action Within 5 Days
PHARMACY LEVEL RECALL

Date: 21 October 2010

EL (10)A/22

Our Ref: MDR 47-10/10

Dear Healthcare Professional,

GlaxoSmithKline / Parallel Distributors

Avandia 4mg

Avandia 8mg

Avandamet 1mg/500mg*

Avandamet 2mg/500mg

Avandamet 2mg/1000mg

Avandamet 4mg/1000mg

(Rosiglitazone / Rosiglitazone + Metformin)

***Product parallel distributed only**

Following the European Medicines Agency (EMA) recommendation on 23rd September 2010 to suspend Marketing Authorisations for all products containing rosiglitazone across Europe, GlaxoSmithKline (GSK) announced in their letter to Healthcare Providers dated 1st October 2010 that all presentations of Avandia and Avandamet would no longer be available after 21st October 2010. All undispensed UK packs purchased through their approved suppliers, Alliance Healthcare and AAH Pharmaceuticals, are being recalled.

MHRA Distribution:

Regional Contacts for NHS Trusts and Provider Units

Chief Pharmacists: England, Scotland, Wales, Northern Ireland

Prison Health Policy Unit (DH)

Chief Pharmacists: Jersey, Guernsey, Alderney, Sark, Isle of Man, Gibraltar

Special Hospitals

Healthcare Commission for distribution to Independent Health Care Establishments

Primary Care Trusts (England)

Medicines and Healthcare products Regulatory Agency (MHRA)

151 Buckingham Palace Road London SW1W 9SZ UK

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An executive agency of the Department of Health



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They should be returned via the relevant wholesaler. Please contact GSK Customer Services on 0800 221 441 for stock return enquiries.

All parallel distributed presentations containing rosiglitazone are also within the scope of this recall. These should be returned to the relevant importer via the wholesaler from which they were originally obtained.

For **all** medical information enquiries, please contact GSK Medical Information on 0800 221 441

Recipients of this Drug Alert should bring it to the attention of relevant contacts by copy of this letter. Primary Care Trusts are asked to forward this to relevant clinics and to general practitioners and community pharmacists for information.

Yours faithfully

Alison Bunce

Pharmaceutical Assessor, DMRC