



**Medicines Authority**  
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## **Drug Alert**

### **CLASS 2 MEDICINES RECALL ACTION WITHIN 48 HOURS**

Date: 17<sup>th</sup> August 2006

Our Ref: MDR 1-8/06

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Dear Managing Pharmacist

Actavis Ltd., Malta

Sertral (Sertraline 50 mg) tablets

MA 245/00401

Batch Number	Expiry date	Pack size	First distributed
84752	30/12/2007	30 tablets	13 <sup>th</sup> July 2007

The Inspectorate and Enforcement Directorate within the Medicines Authority were informed of a Medicinal Product Defect dated 14<sup>th</sup> August 2006 by Actavis Ltd. The reason for the defect is that the PIL (patient information leaflet) was not in compliance to the PIL text approved by the Medicines Authority and had missing drug interactions and side-effects.

The recall is being carried out under the supervision of the Medicines Authority and has been classified as a Class 2 recall up to pharmacy level.

Thanks and regards

Eloise Buontempo  
Medicines Inspector