



**Medicines Authority**  
Inspectorate and Enforcement Division  
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## Drug Alert

### CLASS 3 MEDICINES RECALL

Action Within 5 Days

Date: 1<sup>st</sup> November 2007

Our Ref: MDR 01-10/07

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Dear Healthcare Professional,

**Cipla Ltd**

**Paracetamol tablets 500mg x 1000tabs**  
**(Paracetamol)**

**MA No.: Unlicensed**

Batch Number	Expiry Date	Pack Size	First Distributed
DA6736	11/2009	1000 tabs	22 <sup>nd</sup> January 2007
DA6723	11/2009	1000 tabs	22 <sup>nd</sup> January 2007

Following reports from the Out-Patient's Dispensary SLH and the Government Pharmaceutical Services (GPS) of brown stains on cotton wool in the tablet containers and of similar stains on the Paracetamol tablets, the Inspectorate and Enforcement Directorate within the Medicines Authority started an investigation in collaboration with Cipla Ltd Corporate Quality Assurance (QA) through their local representatives, Drugsales Ltd.

Cipla Ltd QA confirmed that the brown stains are due to rust which contaminated the cotton wool (packaging material of the tablets) during the manufacture of the cotton wool and that the rust stained the Paracetamol 500mg tablets.

Based on this information the Medicines Authority, following consultation with Drugsales Ltd decided to recall both batches. The recall was classified as a Class III Recall.

Yours faithfully

Karl De Marco  
Medicines Inspector