



Medicines Authority
Inspectorate and Enforcement Division
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Drug Alert

CLASS 1 MEDICINES RECALL

Action Now - including out of hours

Date: 4th October 2010

Our Ref: MDR 01-10/10

Dear Healthcare Professional,

George Borg Barthet Ltd.

**Cisplatin Mylan 50mg/50ml(1mg/1ml) solution for infusion
(Cisplatin)**

Batch Number	Expiry Date	Pack Size	First Distributed
3131	10/2013	50mg/50ml	March 2010

The Inspectorate and Enforcement Directorate within the Medicines Authority have been informed of a Medicinal Product Defect warranting a recall by the Responsible Person of George Borg Barthet Ltd. who was in turn informed by the MAH (Mylan SAS France) that the above product was to be recalled. The reason for this recall is that certain vials have a possible presence of black particles of platinum, limited to this batch made from one single batch of glass vial.

This recall was classified as a Class I recall up to patient/ward level by the Medicines Authority.

Health Authorities are asked to bring this information to the attention of Hospital Doctors and Pharmacists as well as Ward Nurses by copy of this letter.

Yours faithfully

Muriel Giglio

Medicines Inspector

Medicines Authority