**Medicines Authority**

**Inspectorate and Enforcement Division**
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# Drug Alert

## CLASS 1 MEDICINES RECALL

### Action Now - including out of hours

Date: 17th December 2010 Our Ref: MDR 04-12/10

Dear Healthcare Professional,

**Drugsales Ltd.**

**Dianeal PD1 Glucose 1.36% 2L solution for peritoneal dialysis MA 161/01101**

| Batch Number | Expiry Date | Pack Size | First Distributed |
|---|---|---|---|
| 10I20G44 | 08/2012 | 1 x 2L | 19th November2010 |

The Inspectorate and Enforcement Directorate within the Medicines Authority have been informed by the Responsible Person of Drugsales Ltd. that following routine product testing and an extensive investigation Baxter has determined that several batches of dialysis solutions produced on a specific manufacturing line have elevated levels of endotoxin in some units even though the products met all specifications at release. To ensure continuous supply of the critical solutions, it was decided not to recall the impacted released batches with the exception of one batch of Dianeal PDI for which an increase in the number of peritonitis cases has been observed. This batch has not been distributed to the renal unit and consequently to patients in Malta.

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, Pharmacists and Nurses who are involved with renal dialysis patients by copy of this letter.

Yours faithfully

Muriel Giglio

Medicines Inspector

Medicines Authority