

Drug Alert

CLASS 3 MEDICINES RECALL

Action Within 5 Days

Date: 12th September 2007

Our Ref: MDR 1-09/07

Dear Healthcare Professional,

Drugsales Ltd.

Platosin 1mg/ml injection fluid , 10ml (Cisplatin)

| Batch Number | Expiry Date | Pack Size | First Distributed |
|--------------|-------------|-----------|-------------------|
| 06G13MA | 07/2009 | X 1 | 04/10/2006 |
| 06G13ME | 07/2009 | X 1 | 02/02/2007 |
| 06G13MF | 07/2009 | X 1 | 29/05/2007 |

The Inspectorate and Enforcement Directorate within the Medicines Authority were informed by the Responsible Person of Drugsales Ltd., who is the local representative of the Marketing Authorisation holder Pharmachemie, that during the on-going stability programme of Platosin 1mg/ml **10ml**, out-of-specification results were found for the degradation product TCAP (trichloroamineplatinatate) after 18 months. Therefore Pharmachemie decided to reduce the shelf-life of cisplatin 1mg/ml 10ml from 36 months (NL) to 18 months. The **50ml** and **100ml** presentations of cisplatin 1mg/ml remain within specifications for TCAP during 36 months. Following this, a Rapid Alert Notification was issued by the Dutch Inspectorate who advised to recall batches having a 36 month expiry label.

Drugsales Ltd. have confirmed that 3 batches of such product have been distributed to the Government Pharmaceutical Services and in collaboration with the Medicines Authority have decided to recall all 3 batches.

Yours faithfully

Muriel Giglio

Medicines Inspector