



**Medicines Authority**  
Inspectorate and Enforcement Division  
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Ref:D004/04

## Drug Alert

### MEDICINES RECALL

Date: 18<sup>th</sup> August 2011

Our Ref: MDR 04-12/10

Dear Healthcare Professional

**Drugsales Ltd.**

**Dianeal PD4 Glucose 1.36% w/v 13.6mg/ml solution  
for peritoneal dialysis** **MA 161/01104**

**Dianeal PD4 Glucose 2.27% w/v 22.7mg/ml solution  
for peritoneal dialysis** **MA 161/01105**

**Extraneal (Icodextrin 7.5%) solution for peritoneal  
dialysis** **MA 161/01201**

Batch Number	Expiry Date	Pack Size	First Distributed
Dianeal PD4 -1.5% equivalent to 1.36% - W1C30T0	March 2013	5 x 2L	10 <sup>th</sup> June 2011
Dianeal PD4 – 1.5% equivalent to 1.36% - W1D26T0	April 2013	5 x 2 L	21 <sup>st</sup> July 2011
Dianeal PD4 – 2.5% equivalent to 2.27% - W1D06T0	April 2013	5 x 2 L	10 <sup>th</sup> June 2011
Extraneal 2.0 Litres – W1C24T1	March 2012	5 x 2 L	27 <sup>th</sup> May 2011
Extraneal 2.0 Litres – W1C24T1A	March 2012	5 x 2 L	27 <sup>th</sup> May 2011
Extraneal 2.0 Litres – W1C28T1	March 2012	5 x 2 L	27 <sup>th</sup> May 2011
Extraneal 2.0 Litres – W1D28T1	April 2012	5 x 2 L	10 <sup>th</sup> June 2011
Extraneal 2.0 Litres – W1E09T2	May 2012	5 x 2 L	29 <sup>th</sup> July 2011
Extraneal 2.0 Litres – W1D13T1	April 2012	5 x 2L	6 <sup>th</sup> June 2011



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The Inspectorate and Enforcement Directorate within the Medicines Authority have been informed by the Responsible Person of Drugsales Ltd. that a voluntary recall up to patient level will be affected on the batches mentioned above for Dianeal and Extraneal products due to the receipt of an increased number of complaints of bag leaks in the area of administration and injection ports.

There have been 3 cases of leaking that also had adverse events reported. Two of these reports were peritonitis episodes associated with the patient continuing to use a bag known to be leaking during the CAPD exchange procedure. In addition there were also 2 medication errors with no associated adverse event related to this issue. Clinical use of leaking Twin Bag product with or without patient/provider recognition of leakage can lead to peritonitis. To date there has only been 1 reported case of a leaking bag of Dianeal 1.36% in Malta.

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