



Medicines Authority
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Drug Alert

CLASS 2 MEDICINES RECALL

Action Within 48 Hours

Date: 17th May 2012

Our Ref: MDR 16-03/12

Dear Healthcare Professional,

ViaSpan solution for organ preservation

Batch Number	Expiry Date	Pack Size	First Distributed
All batches manufactured since July 2011	Not applicable	1 x 1 litre	Not applicable

A potential for ViaSpan contamination by *Bacillus cereus* during the manufacturing process was discovered following routine testing procedures and investigations by the production site (Fresenius Kabi Austria GmbH). At the present time, there is no evidence of contamination in the ViaSpan that has been released to the market. However a decision has been taken by the Medicines Authority that all batches of ViaSpan solution manufactured since July 2011 are recalled considering that an alternative product is available which has already been supplied to Mater Dei Hospital Pharmacy.

Health Authorities are asked to bring this information to the attention of consultants, doctors and nurses who are in contact with patients requiring such treatment by copy of this letter.

Yours faithfully
Muriel Giglio
Medicines Inspector