



April 6, 2012

Dear Healthcare Professional,

Teva Pharmaceuticals USA (under the Duramed label) would like to inform you of an Urgent Medical Device Recall regarding ViaSpan® solution which has an intended use of flushing and cold storage of organs including kidney, liver, and pancreas at the time of their removal from the donor in preparation for storage, transportation and eventual transplantation into a recipient. This product is manufactured by a third party, Fresenius Kabi Austria, for Teva. Teva distributes this product in the U.S. and Canada only.

Summary

- A potential for ViaSpan contamination by *Bacillus cereus* during the manufacturing process was discovered following routine testing procedures and investigations by the production site.
- At the present time, there is no evidence of contamination in the ViaSpan that has been released to the marketplace. We have also received no adverse events to date.
- Teva Pharmaceuticals (Duramed) has decided, as a precautionary measure to recall all batches/lots of potentially affected ViaSpan in the U.S. and Canada.

Below is a list of affected lots. **These lots were distributed between December, 2011 and March, 2012.**

Lot #	Exp. Date	Product Code	Size
16EK0007	10/2012	1000-46-06	10 x 1000mL Bags
16EK0193	10/2012	1000-46-06	10 x 1000mL Bags

If you have these lots, please refer to the attached Urgent Medical Device Recall that was issued on March 30, 2012 for further instruction.

Teva believes there are alternative solutions for organ preservation available, the selection of which should be based on the appropriate clinical judgment of the healthcare provider. Below follows guidance for those cases where patients recently underwent or will undergo organ transplantation, in which ViaSpan has or will be used as an organ preservation solution. For each individual case the healthcare providers should use appropriate clinical judgment in the care of their patients.

- As a precautionary measure, close medical monitoring is recommended for any patients who recently underwent an organ transplantation in which ViaSpan had been used as an organ preservation solution.

- Health care personnel working in transplant units should be alert and vigilant to detect any signs and symptoms of systemic as well as local infections (central nervous system, heart, respiratory or cutaneous) occurring in those post-transplant patients.
- All necessary usual medical measures to characterize and treat infections, as well as to preserve newly transplanted organs, should be undertaken in conformity with the standard of care in place at any given institution (transplant center, hospital).

Further information on recommendations to healthcare professionals

- *Bacillus cereus* is a Gram-positive aerobic or facultatively anaerobic, motile, spore-forming, rod-shaped bacterium which can cause a number of systemic and local, non-gastrointestinal-tract infections in susceptible patients, such as individuals who are immunologically compromised transplant recipients, that may lead to organ rejection and/or other severe medical conditions.
- Antimicrobials noted to be effective in the empirical management of a *Bacillus cereus* infection while awaiting antimicrobial susceptibility results for the isolate include ciprofloxacin and vancomycin. Antimicrobial treatment of *Bacillus cereus* infections should take into account local infectious disease knowledge and practices.

Adverse Event Reporting

Adverse events that may be related to the use of this product may be reported to FDA's MedWatch Adverse Event Reporting Program either online, by regular mail or by fax:

- **Online:** <http://www.fda.gov/MedWatch/report.htm>
- **Regular Mail:** use postage-paid, pre-addressed Form FDA 3500 available at: <http://www.fda.gov/MedWatch/getforms.htm> Mail to address on the pre-addressed form.
- **Fax:** 1-800-FDA-0178

Any Adverse Events should be reported to Teva at 1-866-262-1243 or via email at drug.safety@tevausa.com

Further Information:

Should you have any questions regarding the use of ViaSpan, please contact Teva Pharmaceuticals at 1-866-262-1243.

Regards,



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Teva Pharmaceuticals