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Press Office

Press release

European Medicines Agency recommends action plan to deal with possible presence of endotoxins in Baxter peritoneal dialysis solutions

The European Medicines Agency has been informed by Baxter of the potential presence of endotoxins in their peritoneal dialysis solutions Dianeal, Extraneal and Nutrineal. These are sterile solutions used in patients who have to undergo peritoneal dialysis because of kidney failure.

Although the number of batches affected is likely to be low, the Agency's Committee for Medicinal Products for Human Use (CHMP) has concluded that current stocks should be replaced, because it is not possible to identify which bags are affected and there is a risk that patients who receive peritoneal solutions that contain endotoxins may develop aseptic peritonitis. The replacement of batches should be handled in such a way that vulnerable patients who rely on a particular type of solution are not put at risk. The CHMP has therefore recommended an action plan so that patients who are most in need continue to have access to treatment.

Until all potentially affected batches are withdrawn, prescribers should review their peritoneal dialysis patients to assess the benefit of continuing dialysis as normal while weighing the risk of aseptic peritonitis caused by endotoxins. Various options are available, depending on the dialysis solution and the type of peritoneal dialysis that the patient is using.

Patients should contact their doctor immediately if they notice any symptoms that suggest they are developing aseptic peritonitis (e.g. cloudy effluent seen in drain bag at the end of dialysis, abdominal pain, nausea, vomiting and possibly fever).

The CHMP has asked the company to step up its monitoring systems to ensure that any impact on existing users of the presence of endotoxins in the solutions is identified as quickly as possible. In particular, the company is recommended to report to national competent authorities on a weekly basis all side effects with Dianeal, Extraneal and Nutrineal that are likely to be linked to aseptic peritonitis.

The problem was detected when Baxter found during routine testing at their Castlebar manufacturing plant in Ireland that a number of batches contained unexpected levels of endotoxins (toxic substances from bacterial cell debris). In a root cause analysis the company detected that two of the tanks used in

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the production process had microscopic cracks where endotoxin-producing bacteria had settled. The tanks were taken out of the production line and the company has reviewed its procedures to minimise the risk of the problem happening again.

Baxter is putting in place a plan through which the batches of Dianeal, Extraneal and Nutrineal that potentially contain endotoxins will be removed from the market, once newly produced solutions are made available. If there is evidence that a particular batch is associated with aseptic peritonitis, the company and national competent authorities are recommended to take appropriate measures to remove it from the market. The manufacturer has committed to step up the production of Extraneal, Dianeal and Nutrineal so that stock can be prepared as quickly as possible to replace the batches that cannot be used. It is expected that the replacement should be concluded by March 2011.

Notes

1. This press release, together with all related documents, is available on the Agency's website.
2. A question and answer document with more information is available.
3. The procedure was carried out under Article 5(3) of Regulation (EC) 726/2004.
4. More information on the work of the European Medicines Agency can be found on its website: www.ema.europa.eu

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