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Inductos to be suspended in the EU

Suspension will remain until manufacturing issues are resolved

On 22 October 2015, the European Medicines Agency (EMA) recommended the suspension of Inductos, an implant used to help new bone develop in patients with spinal disc problems and leg fractures. Inductos will remain suspended until issues with the manufacturing site for one of the components of Inductos (an absorbable sponge) are resolved.

EMA started a review of Inductos following an inspection by Dutch and Spanish authorities which found the manufacturing site of the absorbable sponge to be non-compliant with manufacturing requirements. The inspectors noted that the manufacturer, located in the United States, did not have adequate measures in place to prevent particle contamination of the sponges.

Although there is no indication of risk to patients linked to the inspection findings, EMA's Committee for Medicinal Products for Human Use (CHMP) considered that the quality of Inductos cannot be assured with the current manufacturing process. The CHMP therefore concluded that Inductos should be suspended until the manufacturing issues are satisfactorily addressed.

The CHMP recommendation was sent to the European Commission, which endorsed it and issued a final legally binding decision.

Information for patients and healthcare professionals

- Problems have been identified with the way the absorbable sponge in Inductos is manufactured.
- Although there is no indication of risk to patients, Inductos has been suspended and will no longer be available in the EU until issues with the manufacturing site for the absorbable sponge are solved.
- There are alternative treatments available in the EU.
- Patients who have any questions or concerns should speak to their healthcare professional.

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More about the medicine

Inductos is available as a kit for implant containing a powder, solvent and absorbable collagen sponge (or matrix). It is used during surgery in patients with damaged spinal discs or leg (tibia) fractures.

The active substance is dibotermin alfa, a protein that acts on the bone structure and helps with the formation of new bone tissue. The new bone tissue grows into the sponge, which is gradually degraded by the body.

Inductos was authorised centrally in the EU in September 2002.

More about the procedure

The review of Inductos was initiated on 23 July 2015 at the request of the European Commission, under Article 20 of Regulation (EC) No 726/2004. It was carried out by the Committee for Medicinal Products for Human Use (CHMP), responsible for questions concerning medicines for human use. The CHMP opinion was forwarded to the European Commission, which issued a final legally binding decision applicable in all EU Member States on 20/11/2015.

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