Medtronic BioPharma B.V.
Earl Bakkenstraat 10
6422 PJ Heerlen
Netherlands

12 August 2015

Drug shortage for InductOs 1.5 mg/ml powder, solvent and matrix for implantation matrix

Dear Healthcare professional,

Medtronic BioPharma B.V. would like to inform you of the following:

Summary

- No new batches of InductOs can be produced for the European Union because of manufacturing problems for the supplier of the absorbable collagen matrix.
- InductOs is expected to run out of stock as of the end of October 2015.
- No new risks for the patient have been identified in relation to this manufacturing issue. Any product you currently have or will receive can still be used.
- Medtronic BioPharma B.V. is not aware of other pharmaceutical products with a similar pharmacological action as InductOs.
- Medtronic BioPharma B.V. is working closely with the matrix supplier to resolve the issues and will inform you once InductOs becomes available again.

This information is sent to you in agreement with the European Medicines Agency (EMA) and the Medicines and Healthcare products Regulatory Agency (MHRA).

Further information on the drug shortage and recommendations

This letter is sent to you as you have potentially used InductOs 1.5 mg/ml powder, solvent and matrix for implantation matrix. Medtronic BioPharma B.V., the Market Authorisation Holder, in agreement with the EMA and the MHRA would like to inform you of a drug shortage for InductOs 1.5 mg/ml powder, solvent and matrix for implantation matrix.

A recent inspection of the manufacturer who supplies the absorbable collagen matrix used to make InductOs identified inadequacies in the measures in place to prevent particulate contamination. This means Medtronic BioPharma cannot produce new batches of InductOs at present.

A review of the available information has not led to new concerns related to the safety of the product. Any InductOs package that you currently have can be used to treat patients.

With the currently available inventory of InductOs, Medtronic BioPharma B.V. expects to run out of stock as of the end of October 2015.

We are not aware of any alternative medicinal products with a similar pharmacological action to InductOs. You should consider using alternative techniques in line with clinical practice when InductOs is not available.

Medtronic BioPharma B.V. is working closely with the matrix supplier to resolve the issues and limit the shortage of InductOs. Meanwhile, we ask you to consider prioritising InductOs use for patients with a reduction in their osteogenic capacity or where autograft is unavailable. Medtronic BioPharma B.V. will inform you once InductOs becomes available again.

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We kindly ask you to forward this letter to other healthcare professionals who might be affected by this potential drug shortage.

Indication

InductOs 1.5 mg/ml powder, solvent and matrix for implantation matrix is indicated for:

- single-level lumbar interbody spine fusion as a substitute for autogenous bone graft in adults with degenerative disc disease who have had at least 6 months of non-operative treatment for this condition.
- the treatment of acute tibia fractures in adults, as an adjunct to standard care using open fracture reduction and intramedullary unreamed nail fixation.

Call for reporting

Please report suspected adverse reactions with any medicine or vaccine to the Medicines and Healthcare Products Regulatory Agency (MHRA) through the Yellow Card Scheme online at https://yellowcard.mhra.gov.uk/. Alternatively, prepaid Yellow Cards for reporting are available:

- upon request by mail: "FREEPOST YELLOW CARD"
- at the back of the British National Formulary (BNF)
- by telephoning the Commission of Human Medicines (CHM) free phone line: 0800 731 6789
- or by electronic download through the Yellow Card section of the MHRA website https://yellowcard.mhra.gov.uk/downloadable-information/

When reporting, please provide as much information as possible, including information about medical history, any concomitant medication, onset and treatment dates.

Any suspected adverse reactions with InductOs may also be reported to Medtronic BioPharma B.V. via telephone at 0808 234 01 68 or via email biopharmamedicalinformation@medtronic.com.

Contact information

If you need assistance or if you have any related questions or concerns, please contact Medtronic BioPharma B.V.'s Medical Information Service, Tel. 0808 234 01 68 or email: biopharmamedicalinformation@medtronic.com.

Best Regards,

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Koen van der Heijden
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