5th November 2015

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

Dear Healthcare professional,

Following the letter sent 12 August 2015 on potential drug shortage for InductOs 1.5 mg/ml powder, solvent and matrix for implantation matrix, Medtronic BioPharma B.V. would like to inform you that the shortage has occurred earlier than expected and that the product is now out of stock.

This letter is sent to you as you have potentially used InductOs 1.5 mg/ml powder, solvent and matrix for implantation matrix in the past. This information is sent to you in agreement with the European Medicines Agency and the Medicines and Healthcare products Regulatory Agency (MHRA).

Further information on the potential drug shortage and recommendations

A recent Good Manufacturing Practices (GMP) inspection of the manufacturer of the absorbable collagen matrix used in InductOs identified inadequacies in the measures used to prevent particulate contamination. This means Medtronic BioPharma currently cannot produce new batches of InductOs.

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

We are not aware of any alternative medicinal products with a similar pharmacological action to that of InductOs. We advise you to consider using other alternatives in line with your clinical practice while InductOs is not available.

We are working closely with the matrix supplier to resolve the production and supply issues to limit the shortage of InductOs. We will inform you once InductOs becomes available again.

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