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

12 August 2015

Potential drug shortage for InductOs (dibotermin alfa) 1.5 mg/ml powder, solvent and matrix for implantation matrix

Dear Healthcare professional,

Medtronic BioPharma B.V., in agreement with the European Medicines Agency and the Health Products Regulatory Authority (HPRA) 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.
- As a result InductOs is expected to run out of stock as of the end of October 2015.
- No risks for the patient associated with this issue have been identified. 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.

Further information on the potential 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 in the past. Medtronic BioPharma B.V., the Market Authorisation Holder, in agreement with the European Medicines Agency (EMA) and the HPRA would like to inform you of a potential drug shortage for InductOs 1.5 mg/ml powder, solvent and matrix for implantation matrix.

In a recent Good Manufacturing Practices (GMP) inspection of the manufacturer of the absorbable collagen matrix used in InductOs, non-compliances with the EU GMP regulation were found showing that measures to prevent particulate contamination were not adequate. Therefore the GMP certificate of the supplier has not been renewed. This means Medtronic BioPharma can no longer produce new batches of InductOs at this time.

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.

There are no alternative medicinal products with a similar pharmacological action as InductOs. You should consider using other alternatives in line with your 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. Medtronic BioPharma B.V. 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 potential drug shortage.

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

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.

Adverse Event reporting

Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via the national reporting system:

HPRA Pharmacovigilance
Earlsfort Terrace
IRL - Dublin 2
Tel: +353 1 6764971
Fax: +353 1 6762517
Website: www.hpra.ie
e-mail: medsafety@hpra.ie

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. 1800 554 629 or email: biopharmamedicalinformation@medtronic.com.

Best Regards,

Isabelle de Chambrier
Qualified Person | Medtronic BioPharma B.V.

Koen van der Heijden
Qualified Person for PharmacoVigilance | Medtronic BioPharma B.V.