



EMA/495296/2015 Rev.1

Update of 15 August 2017:

The shortage affecting Inductos has been resolved and the below information and recommendations which were issued during the shortage no longer apply.

16 September 2015

**Shortage of Inductos (dibotermin alfa)
Powder, solvent and matrix for implantation matrix**

Indication	Inductos is used for surgical implantation in patients treated for damaged spinal discs or leg (tibia) fractures.
Reason for shortage	<p>During an inspection at the manufacturing site for one of the components of Inductos (the absorbable sponge), it was noticed that there was a potential for particles to be present in the sponge. The certificate of Good Manufacturing Practice was therefore withdrawn from the site, and as a result further batches of the sponge cannot be imported into the EU. As this site is the only site that produces Inductos's sponge, stocks of Inductos are expected to run low in the EU.</p> <p>There is no indication of risk to patients linked to the findings at the site.</p>
Member States affected¹	Austria, Belgium, Denmark, Finland, Germany, France, Ireland, Italy, Luxemburg, Netherlands, Norway, Portugal, Spain, Sweden and the United Kingdom.
Information to healthcare professionals	<ul style="list-style-type: none">• Shortages of Inductos are expected in some EU Member States from mid-September 2015;• In the event of a shortage, consider alternative treatments;• Additional advice may be available from the national competent authority.

¹ This information may change. For accurate information about the status of a medicine shortage in a particular Member State the national competent authority should be contacted.



Shortage of Inductos (dibotermin alfa) Powder, solvent and matrix for implantation matrix

Information to patients

- Shortages of Inductos are expected in some EU Member States from mid-September 2015.
- There are alternative treatment options and if you need Inductos your doctor will use an appropriate alternative.
- Patients who have any questions should speak to their doctor or pharmacist.
- Additional advice may be available from the [national competent authority](#).

Shortage resolved