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Shortage of Apidra (insulin glulisine) cartridges

The European Medicines Agency is aware of a shortage of Apidra, a medicine for treating diabetes, affecting the supply of Apidra 3 ml cartridges and Apidra prefilled disposable pens (OptiSet and SoloStar) in several EU Member States. The Agency's Committee for Medicinal Products for Human Use (CHMP) has made several recommendations to manage the situation and ensure patients continue to receive appropriate treatment during the temporary supply shortage.

What is Apidra?

Apidra is a solution for injection that contains the active substance insulin glulisine. It is used to treat patients aged six years or over with diabetes, when they need insulin.

Apidra is supplied in vials, cartridges and prefilled disposable pens (called OptiSet and SoloStar). Apidra is given by injection under the skin or by continuous infusion with an insulin pump. The vials are used together with an insulin syringe to inject the medicine, or with an insulin pump. The cartridges are used together with a pen device[1] to inject the medicine. The prefilled pens are used alone to inject the medicine.

Apidra is a rapid-acting insulin analogue (chemically modified insulin) that is used in combination with intermediate- or long-acting insulins or insulin analogues. It may also be used in combination with other (oral) medicines to treat diabetes.

What is the cause of the supply problem and how long will it last?

The company that markets Apidra, Sanofi-Aventis Deutschland GmbH, informed the Agency that an accidental spillage occurred on 11 July 2011 at the plant where the medicine is manufactured in Frankfurt, Germany. Manufacturing has been temporarily suspended while internal investigations are taking place. This will result in a continued delay in the release of batches of Apidra cartridges onto the EU market. The shortage affects Apidra cartridges and Apidra prefilled disposable pens, OptiSet and SoloStar. It does not affect Apidra vials or any other Sanofi insulin product (Lantus and Insuman).

[1] Cartridges are suitable for use with OptiPen, ClikSTAR, Tactipen or Autopen 24, and specific cartridges are suitable for use with OptiClik.

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Normal supply is expected to resume in early 2012. Supply shortages are expected in most EU Member States until normal supply resumes.

What are the recommendations of the CHMP to cope with the shortage?

Apidra cartridges and prefilled disposable pens currently on the market are safe to use.

The Committee has agreed that the company should provide a letter to the healthcare professionals, health authorities and wholesalers explaining the specific supply situation in their countries together with recommendations to manage the situation. During the supply shortage, if cartridges or prefilled pens are not available, the main recommendations are as follows taking account of national guidance and the needs of individual patients:

- Patients may be switched to an alternative rapid-acting insulin analogue – i.e. Humalog (insulin lispro) or NovoRapid (insulin aspart) under the supervision of a healthcare professional and with close monitoring of blood glucose levels.
- Where rapid-acting insulin analogues are not available or not appropriate, patients may need to be switched to regular (standard) short-acting human insulin such as Insuman, Humulin, Novolin or equivalent. As these insulins have a slower onset and a longer duration of action than Apidra, this must be done under the direct supervision of a healthcare professional with more frequent monitoring of blood glucose levels and adjusted dose as required.
- Patients for whom vials and syringes are an acceptable alternative to a pen device may be switched to Apidra vials and syringes if available. No dose adjustment is required.

The company is providing a program of support for healthcare professionals and patients during the supply shortage, including a demonstration video and educational materials on switching to using vials and syringes, rapid-acting insulin analogues or regular short-acting human insulin. The company will also provide a national helpline for patients and healthcare professionals in the countries concerned.

The Committee is working closely with Sanofi-Aventis Deutschland GmbH to ensure that normal supply is resumed as soon as possible in the interest of patients.

The current European public assessment report for Apidra can be found on the Agency's website: ema.europa.eu/Find medicine/Human medicines/European Public Assessment Reports.