



IMPORTANT PATIENT INFORMATION
Switching from Apidra™ (insulin glulisine) 3ml Cartridges/Pens
to Apidra™ vial and syringe

PATIENTS - PLEASE READ THIS CAREFULLY

November 2011

Dear Apidra™ user

Your Apidra™ SoloStar™ and Apidra™ cartridges (insulin glulisine) will be temporarily unavailable from the end of November, 2011

As your physician/pharmacy/DNE or other healthcare professional may have already told you, we regret to inform you that SANOFI will not be able to supply you with **Apidra™ SoloStar™ and Apidra™ cartridges (insulin glulisine)** from the end of November 2011. This is a **temporary** supply issue.

This was due to a technical issue that occurred at the manufacturing site in Frankfurt, Germany. There is no safety issue with the actual insulin. However as your safety is paramount, production of the cartridges/pens has been stopped and corrective actions are being implemented.

SANOFI are working round the clock to re-commence production and expect availability of **Apidra™ SoloStar™ and Apidra™ cartridges (insulin glulisine)** in the near future. As mentioned before, this is a **temporary** shortage.

Your safety and well-being is the highest priority for Sanofi, and we are committed to providing high-quality insulins.

With that in mind, from the **end of November 2011**, SANOFI will be implementing an extensive switch campaign to support the **temporary** conversion from your current **Apidra™ SoloStar™ or Apidra™ cartridges** over to the use of **Apidra™ vials and syringes**.

When you refill your next Apidra™ script, via your normal process you will be provided with an **Apidra™ Switch Pack**. This will include the following to assist and support you. Please ensure that you request the pack when you fill your next Apidra™ script. Please note that there is one pack per patient and will only be issued with your **FIRST** script of the Apidra™ vial

1. Instructional step-by-step DVD guide with visuals and animation to assist you in the use of Apidra™ via the vial and syringe method
2. Illustrated manual to assist you and guide you on the use of Apidra™ via a vial and syringe
3. Contact details for the SANOFI Apidra™ Hot Line (0800 111 022) – this is an automated call centre. When you call, based on where you live, you will be directed to a qualified Diabetic Nurse Educator to assist you with the switch to using a vial and syringe
4. 60 insulin 0.5ml syringes to assist you with the switch over to vial and syringe use

We appreciate that this is an inconvenience, however we encourage you to remain on your Apidra™ (via the vial and syringe) as there are distinct benefits in NOT switching to another short acting insulin, viz^{1,2,3,4}:

- no change in the active substance – you will still be using the same insulin that you and your body are used to
- no dose adjustment: as it is the same insulin, just in a different device, you can maintain the EXACT same dosing that you are currently using
- known immunogenic profile for a given individual: this means less of chance of reactions as you are staying on the same insulin
- familiarity with product: you trust and know Apidra™
- less risk of hypo- or hyperglycaemias (which can occur if you change insulins)
- no need to increase your daily blood glucose monitoring (which you might have to do if you change insulins)



Please bear in mind, that your Health Care Professional is the **ONLY** one that should consider switching you over to another short-acting insulin.

All other SANOFI insulin products (Lantus® and Insuman®) are not affected at all as they are manufactured and filled on separate lines, in different plants to Apidra™ cartridges.

SANOFI have had extensive consultations with most major Medical Aids, as well as distribution channels to ensure that you have a seamless switch from your current **Apidra™ SoloStar™ or Apidra™ cartridges** when you fill your script over to the **Apidra™ vials and syringes**.

Once again, we sincerely apologise for the inconvenience and thank you for your continued support.

We will keep your health care professionals updated on the situation and availability of stock of the pens and cartridges.

Best regards,

A handwritten signature in black ink, appearing to read 'W. Riback', enclosed within a circular scribble.

Dr Wayne Riback
Senior Medical Advisor
SANOFI

A handwritten signature in black ink, appearing to read 'Pieter Taljaard', with a long horizontal flourish extending to the right.

Pieter Taljaard
Brand Manager - Insulins
SANOFI

References:

1. Apidra™ South African registered Package Insert
2. Insulin Aspart (NovoRapid™) registered global Package Insert
3. Humalog® registered global Package Insert
4. Humulin R® registered global Package Insert