

Prescribing and Clinical Effectiveness Bulletin

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This *Bulletin* provides an update on the current supply problems affecting insulin glulisine (Apidra) and on the planned discontinuation of Opticlik, Opticlik Pro 1 and Optiset insulin pen devices.

SUPPLY PROBLEMS WITH INSULIN GLULISINE (APIDRA)

Summary

- No new patients should be commenced on insulin glulisine (Apidra) until continuity of supply can be assured. This is not expected to be the case until the end of December 2011.
- Practices should contact all patients currently receiving supplies of Apidra Optiset prefilled pens, Apidra SoloSTAR prefilled pens, Apidra ClikSTAR cartridges and Apidra Opticlik cartridges and check what levels of stock these patients have.
- Supplies of Apidra® insulin vials are not affected.
- Sanofi- Aventis have pledged to ensure continuing supplies of insulin glulisine for those classed as vulnerable patients (age under 18 years, over 70 years, pregnant patients or those classed as having brittle diabetes who have failed to respond to previous treatment with rapid acting insulin. Prescribers are urged to contact Sanofi Customer Services to arrange ongoing supplies for these patients.
- Due to a decrease in demand there should be enough Apidra Opticlik cartridges to meet the needs of patients currently receiving this product. However it is advisable to contact Sanofi Customer Services to confirm this before issuing a new prescription.
- For all other patients not classed as vulnerable who do not have sufficient supplies of Apidra to last until new stock becomes available, arrangements will need to be made for them to receive either supplies of Apidra insulin vials if this is judged to be appropriate by their clinician or to be switched to an alternative rapid acting insulin analogue.
- Suitable alternative products might be insulin aspart (NovoRapid®) or insulin lispro (Humalog®). Further advice on appropriate alternative products and doses can be obtained from the Sanofi-Aventis Medical Information service or the Lincolnshire Community Diabetes team. The usual recommendation, if switching to alternative insulin, is to reduce the current dose by 10-20% and titrate according to response. However this will vary according to individual patient circumstances and all prescribers are advised to seek advice if they are not experienced in changing insulin therapy.

- Contact details are provided at the end of this *Bulletin* to assist prescribers, community pharmacists and GP dispensers in locating supplies for existing patients.
- Further updates will be provided on the ongoing supply situation of Apidra insulin through the *PACE Bulletin*.

DISCONTINUATION OF OPTICLIK, OPTIPEN PRO 1 AND OPTISET INSULIN PEN DEVICES PLANNED FOR DECEMBER 2011

Summary

- Sanofi–Aventis is reducing its range of insulin pen devices. From December 31st 2011, the pre-filled disposable device OptiSet® and the re-useable devices OptiClik® and OptiPen Pro 1® will no longer be available.
- All patients currently using insulin glargine (Lantus®) or the Sanofi-Aventis range of human insulins (Insuman®) need to be reviewed and, if they are currently using one of the affected pen devices, switched to an alternative.
- All of the current range of insulins will be available for use in the re-useable device ClikSTAR®. The insulin for this device is available in 3ml cartridges.
- Insulin glargine (Lantus®) and the human insulins Insuman Comb 25® and Insuman Basal® will be available in the SoloSTAR® range of pre-filled disposable devices.
- The human insulins Insuman Rapid®, Insuman Comb 15® and Insuman Comb 50® will no longer be available in a pre-filled disposable device. All patients currently receiving these insulins will need to be reviewed and, if appropriate, switched to the ClikSTAR® re-useable device.
- The Autopen 24® pen re-useable device will no longer be supplied by Sanofi-Aventis but will be available directly from Owen Mumford. The ClikSTAR® cartridge can be used with this pen device.
- All health care professional have been sent written information from Sanofi Aventis advising them of the changes in availability of insulin pen devices and provided with copies of patient information leaflets to help facilitate the change.

SUPPLY PROBLEMS WITH INSULIN GLULISINE (APIDRA)

Due to manufacturing problems at the Sanofi-Aventis manufacturing site in Frankfurt, there is a temporary shortage of insulin glulisine (Apidra®). Sanofi-Aventis have sent out a letter to all healthcare professionals providing details as to which formulations are affected and have also contacted those dispensing practices and community pharmacies that use higher volumes of this type of insulin.

Availability of Apidra formulations:

Apidra Optiset® and SoloSTAR® prefilled pens	Very limited supplies are available through wholesalers. Existing supplies of Apidra SoloSTAR pens are being reserved for vulnerable patients. Further supplies of Apidra SoloSTAR pens are unlikely to be available until December 2011. There will be no further supplies of the Apidra Optiset device as it is being withdrawn at the end of December 2011.
Apidra ClikSTAR® cartridges	Limited supplies are available through wholesalers. Existing stocks will be exhausted by the middle of October 2011. New supplies will not

Apidra OptiClik® Cartridges	<p>be available until December 2011.</p> <p>Due to the planned withdrawal of the OptiClik pen, there are now only a small number of patients currently using these cartridges. There should be enough stock available in the UK for existing patients to continue on this until the devices planned withdrawal at the end of 2011. All patients currently using OptiClik cartridges should continue using this product until the end of December 2011 when supplies become available of the ClikSTAR cartridges.</p>
Apidra® Solution for injection vials	<p>Supplies of this have not been affected. This may be a suitable alternative for patients previously using other formulations of Apidra. However patients will need both training and support in line with the NPSA advice on the safer use of insulin if they are to switch from a pen device to using vials and syringes. Sanofi-Aventis have provided assurances that there is sufficient supply to meet current demand for existing patients and for those anticipated switching from pen devices to vials for the interim period until supplies of the pre-filled pens and cartridges are restored.</p>

Action to be taken by those currently using affected formulations:

- Practices need to identify all patients currently receiving supplies of Apidra Optiset prefilled pens, Apidra SoloSTAR prefilled pens, Apidra ClikSTAR cartridges and Apidra Opticlik cartridges.
- All patients need to be contacted to determine their current personal stock level.
- Sanofi- Aventis have pledged to ensure continuing supplies of insulin glulisine for those classed as vulnerable patients (those under 18 years or over 70 years or pregnant or those classed as having brittle diabetes unresponsive to previous treatment with rapid acting insulin). Prescribers are urged to contact Sanofi Customer Services on 0800 854 430 to arrange ongoing supplies for these patients. Contact details are provided at the end of this *Bulletin*.
- Sanofi- Aventis are also reserving supplies of insulin glulisine for all patients currently receiving Apidra® as part of a clinical trial (50 sites across UK).
- Due to a decrease in demand there should be enough Apidra Opticlik cartridges to meet the needs of patients currently receiving this product. However if your patient requires further supplies before December 2011 it is advisable to contact Sanofi Customer Services to confirm there is sufficient stock.
- For all other patients not classed as vulnerable who do not have sufficient supplies of Apidra to last until new stock becomes available, arrangements will need to be made for them to receive either supplies of Apidra insulin vials (if this is judged to be appropriate by their clinician) or to be switched to alternative rapid acting insulin analogues. Suitable products might be insulin aspart (NovoRapid®) or insulin lispro (Humalog®).
- Further advice on appropriate alternative products and doses can be obtained from the Sanofi-Aventis Medical Information service or the Lincolnshire Community Diabetes team. The usual recommendation, if switching to an alternative insulin, is to reduce the current dose by 10-20% and titrate according to response. However this will vary according to

individual patient circumstances and all prescribers are advised to seek advice if they are not experienced in changing insulin therapy.

- For those patients switching to Apidra solution in vials Sanofi- Aventis have offered to assist in providing supplies of BD insulin syringes. Practices wishing to access these supplies are advised either to contact the Sanofi Medical Information line or the Sanofi Diabetes Development Executive. Contact details are provided below.

DISCONTINUATION OF OPTICLIK, OPTIPEN PRO 1 AND OPTISET INSULIN PEN DEVICES PLANNED FOR DECEMBER 2011

Introduction

In June 2010, the National Patient Safety Agency (NPSA) issued a Rapid Response Report on the safer administration of insulin. The RRR recommended a series of actions designed to reduce the risk of patient safety incidents linked to the wrong dose of insulin being prescribed, dispensed or administered. These were detailed in the *PACE Bulletin*, Volume 4 No 14 (September 2010).

One of the main recommendations advised that only commercial pen devices or insulin syringes should be used when administering insulin. The RRR went on to highlight the wide range of commercial pen devices available and the differences in the maximum /minimum doses delivered and how the pen operates. A specific example was given of an unintentional overdose involving the incorrect use of an Opticlick® pen device.

As a result of this, Sanofi -Aventis made the decision to rationalise the range of insulin pen devices it produces and to discontinue the following items from the end of December 2011:

- Opticlik®:** This is a **reusable injection device** that is used with Lantus OptiClik® cartridges (insulin glargine 3ml cartridges) or Apidra Opticlik® cartridges (insulin glulisine 3ml cartridges)
- Optipen® Pro 1:** This is a **reusable injection device** that is used with Lantus® cartridges (insulin glargine 3ml cartridges) or Apidra cartridges (insulin glulisine 3ml cartridges) and Insuman®, insulin cartridges.
- Optiset® (Prefilled):** This is a **disposable prefilled injection device**. There are a range of disposable insulin Optiset® pens – Lantus® Optiset® Prefilled Pens (insulin glargine 3ml Prefilled Pens), Apidra® Optiset® Prefilled Pens (insulin glulisine 3ml Prefilled Pens) and Insuman® Optiset® Prefilled Pens .

From December 31st 2011 the only pens available from Sanofi – Aventis will be

- **Pre-filled disposable device - SoloSTAR range**
- **Re-useable pen device - ClikSTAR range**

It is hoped that a reduction in the number of insulin pen devices will help to reduce insulin administration errors which are reported nationally to the NPSA.

Action to be taken by those currently using affected formulations:

- **The withdrawal of these insulin pen devices will potentially affect any patients currently using insulin glargine (Lantus®), insulin glulisine (Apidra®) and human insulin (Insuman®).**
- **Practices will need to identify patients prescribed any of the above insulins and identify anyone using one of the injection devices that will be discontinued.**
- **Due to the current shortage of insulin glulisine (Apidra®) we are not advising that patients are switched from their existing pen devices to the newer pens until the supply problem has been resolved.**
- **The tables below will help you to search for patients using the devices that will be discontinued:**

Prefilled pens

Current Prescription	SWITCH TO
Lantus Optiset® Prefilled Pens (Insulin glargine 3ml Prefilled Pens)	Lantus SoloSTAR® Prefilled Pens (Insulin glargine 3ml Prefilled Pens)
Insuman Basal Optiset® prefilled pens (Human isophane insulin)	Insuman Basal SoloSTAR® Prefilled Pens (Human isophane 3ml Prefilled Pens)
Insuman Comb 25 Optiset® prefilled pens	Insuman Comb 25 SoloSTAR® Prefilled Pens (neutral insulin 25%/ isophane insulin 75% 3ml Prefilled Pens)
Insuman Comb 15 Optiset® prefilled pens, Insuman Comb 50 Optiset® prefilled pens	There is no equivalent SoloSTAR prefilled pen device. Patients will need to be reviewed and switched to Insuman Comb 15/Insuman Comb 50 ClikSTAR Prefilled Pens
Insuman Rapid Optiset® prefilled pens	There is no equivalent SoloSTAR prefilled pen device. Patients will need to be reviewed and switched to Insuman Rapid ClikSTAR Prefilled Pens
For patients prescribed prefilled pens generically you will need to confirm which pen they are currently using – Those using Optiset® Pens will need to switch to a SoloSTAR® pens	

Cartridges (for use with reusable injection device)

Current Prescription	SWITCH TO
Lantus Opticlik® Cartridges (Insulin Glargine 3ml cartridges)	Lantus ClikSTAR® Cartridges (Insulin glargine 3ml cartridges)
Insuman Comb 15, Insuman Comb 25, Insuman Comb 50 , Insuman Basal, Insuman Rapid 3ml cartridges	Insuman Comb 15, Insuman Comb 25, Insuman Comb 50, Insuman Basal, Insuman Rapid ClikSTAR® Cartridges
For patients prescribed cartridges generically you will need to confirm which reusable pen they are currently using. Those using Optipen Pro 1® or Opticlik® pen device will need to switch to a ClikSTAR® pen . Supplies of the new re-useable pen device ClikSTAR can be obtained free of charge from Sanofi Aventis	

- **When reviewing your patients, ensure that they are able to use their new insulin pen device. You may need to consider a different pen device if your patient has difficulty using the proposed new device.**
- **Practices also need to identify patients who are using Autopen® 24 (reusable pen) to administer insulin glargine (Lantus®) or any of the Insuman range of insulins. The Autopen® 24 is not being discontinued, but is no longer being supplied by Sanofi - Aventis. Patients can continue to use this device, but practices need to ensure that these patients are**

prescribed the appropriate ClikSTAR® 3ml Cartridges. Supplies of the pen can be obtained via most wholesalers and also direct from Owen Mumford (telephone number 0800 7316959).

- **The needles recommended for use with the new pens remain unchanged**

Cost impact of product withdrawal

In the majority of cases the switch to an alternative pen device is cost neutral. When switching from the Insuman Comb 25 and Insuman Basal Optiset pre-filled disposable devices to the SoloSTAR device there is an additional cost of £2.30 per 5 x 3ml disposable pens.

Additional information

All healthcare professionals have received letters and leaflets, from Sanofi- Aventis advising of the discontinuation of the pen devices. SystmOne have added a status update for GP practices highlighting which pens are being withdrawn. All dispensing practices and community pharmacies will soon be sent patient information leaflets and pharmacies have a flag on their electronic system. Dispensaries and pharmacies will shortly be getting a leaflet to give to patients when dispensing an old pen too.

Contact details

Sanofi Customer Services	0800 854 430 (9am-5.15pm Monday-Thursday, 9am-4pm Friday)	To confirm if Apidra is available to order:
Sanofi Medical Information	01483 505 515	Any other enquiry including requests to access Apidra for an individual patient for whom no alternative exists.
Laura Meredith, Sanofi Diabetes Development Executive	Mobile 07921 054974	For additional support in obtaining supplies of Apidra insulin
Insulin Support Line	0845 606 6887 (24 hours/day, 7 days/week)	Individual patient enquiries

Acknowledgements

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