

## Biosimilars - Insulin analogues

### Key recommendations

#### Initiation of insulin

##### Type 1 diabetes (T1DM)

- NICE guidance states insulin glargine can be considered as an option in people with T1DM who require insulin.<sup>1</sup>
- In these patients the biosimilar product, Abasaglar®, should be selected in preference to Lantus or other insulin analogues.

##### Type 2 diabetes (T2DM)

- The initiation of insulin in T2DM should be in line with NICE guidance.<sup>2</sup>
- NICE guidance recommends insulin (NPH) isophane is the treatment of choice.
- For patients that meet the requirements for an insulin analogue such as insulin glargine, then Abasaglar®, should be selected in preference to Lantus or other insulin analogues.

#### Switching of insulin

##### Type 1 and type 2 diabetes

- Patients with either T1DM or T2DM should be under regular review to ensure appropriate management of their diabetes and associated complications.
- In patients treated with insulin glargine (Lantus) these reviews provide an ideal opportunity to discuss the possibility of switching to the biosimilar product.
- Ideally this would involve a discussion of the potential benefits as well as any possible risks.
- The patient should be made aware that any switch is only to be undertaken with their consent.
- Patients contemplating a switch will also need to be familiar with the insulin pens currently available from Eli Lilly, i.e. the KwikPen and HumaPen Savvio.
- Training on these devices will be required for patients that have not experienced these pens previously.
- It should be noted that the Boehringer–Lilly Alliance are not seeking to actively promote or support the switching of patients currently receiving Lantus onto Abasaglar®.

#### Prescribing of insulin glargine

- As with all biosimilar products prescribing by brand name is strongly recommended.
- In order to prevent any inadvertent switching, it is also recommended that prescribing of Lantus, is also by brand name only.

#### Clinical evidence

The clinical programme to show biosimilarity between Abasaglar® and Lantus is based on five phase 1 and two phase 3 studies.

The phase 1 studies assessed pharmacokinetic (PK) and pharmacodynamic (PD) parameters. Four studies were in healthy volunteers and one was in patients with T1DM.<sup>3-5</sup> The evidence showed that the PK and PD profiles of both products were similar. In these Phase I studies, Abasaglar® was well-tolerated, with no safety concerns noted in adverse events (AEs), clinical laboratory tests, vital signs or ECG data. The frequency of AEs reported was similar between the two treatments.

The PK study in T1DM assessed Abasaglar®'s duration of action. Results showed that the mean duration of action was 24 and 26 hours for Abasaglar® and Lantus, respectively.<sup>5</sup>

In addition two phase 3 clinical studies were also conducted (ELEMENT-1, ELEMENT-2).<sup>6,7</sup>

ELEMENT-1 was a 52-week, randomised, open-label study of 535 patients with T1DM. ELEMENT-2 was a 24-week, randomised, double-blind study of 756 patients with T2DM.

In both studies the primary objective was to evaluate whether Abasaglar® was non-inferior to Lantus in reducing average blood sugar levels (HbA1c). Anti-insulin glargine antibodies were also measured to determine the immunogenicity profile of Abasaglar®. In each study both products led to significant decreases in average blood glucose levels (HbA1c) with similar reductions seen with in both treatment arms.

There were also similar rates of AEs, including episodes of hypoglycaemia, seen with Lantus and Abasaglar® in both T1DM and T2DM.

The development of insulin antibodies was examined in both studies as well as the impact of these antibodies on clinical outcomes. Results showed a similar immunogenicity profile for the two products and clinical outcomes were not affected regardless of whether antibodies were detected or not.<sup>8</sup>

## Costs/savings

The biosimilar product, Abasaglar®, is to be offered with a 15% discount versus the list price for Lantus. This means the prices for both products will be as follows:

### Insulin glargine - Lantus®

Injection, insulin glargine 100 units/mL, net price

- 10-mL vial = £30.68
- 5 × 3-mL cartridge (for ClikSTAR® and Autopen® 24) = £41.50
- 5 × 3-mL Lantus® SoloStar® prefilled disposable injection devices = £41.50

### Insulin glargine biosimilar - Abasaglar®

Injection, insulin glargine 100 units/ml, net price

- 5 x 3ml cartridge (for HumaPen Savvio) = £35.28
- 5 x 3ml disposable injection devices (for KwikPen) = £35.28

It is estimated using ePACT data that a 100% switch in all English primary care patients could **save £12 million per annum**. (ePACT data July-September 2015).

## References

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Additional resources available



Bulletin



Data pack

[www.prescqipp.info/resources/viewcategory/430-biosimilars-insulin-analogues](http://www.prescqipp.info/resources/viewcategory/430-biosimilars-insulin-analogues)

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