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Biosimilars – new insulin glargine

Summary

- **The patent for insulin glargine (Lantus®) has expired and a biosimilar brand has been launched (Abasaglar®) which is 15% cheaper.**
- **The two products have similar actions, but should not be regarded as interchangeable. Abasaglar® may be appropriate for new patients who need a long-acting insulin or those with suboptimal control who are having a review of their treatment. There is a potential for unexpected hypoglycaemia if patients are inadvertently switched between brands.**
- **The brand that a patient is using should be included in all communications between the GP and hospital, also in the patient's insulin passport.**
- **Prescriptions should always specify the brand to be dispensed (the MHRA recommends this for all biosimilars).**
- **GP practices should identify those patients already using insulin glargine and ensure the brand name Lantus® is included, for repeat prescriptions and to avoid any confusion later.**

Introduction

Biologic medicines are large molecules (often proteins or antibodies) that perform specific pharmacological or therapeutic actions. Examples include hormones (eg growth hormone), drugs used in inflammatory diseases (eg infliximab), therapies for cancer, (eg trastuzumab) and haematologic agents (eg filgrastim). This briefing is intended to provide more information about the new biosimilar insulin glargine (Abasaglar®), launched September 2015.

What is a biosimilar?

A biosimilar is a biologic medicine that has been developed to have a very similar pharmacological effect to that of an original branded biologic products (or 'reference' product) and with the same dose regimen, but it does not have an identical chemical structure. Biosimilars are marketed after the patent for the branded product has expired. Although they might be regarded as 'generic' medicines, they are not chemically identical. The process of licensing for a biosimilar is therefore not the same as for generic drugs. Biosimilars need to be identified by different names even though they have the same therapeutic effect as the original product, this is why it is necessary to use the brand name.

Patent expiry and biologic medicines

Patents for biologic medicines are broadly similar to those for other pharmaceuticals. After a period of exclusivity, other companies can develop products with a similar therapeutic effect, though as noted above their chemical structures are not identical to the reference product.

How are biosimilars introduced and regulated?

Biosimilars undergo broadly the same process for approval by the European Medicines Agency (EMA) as other generic pharmaceuticals, although there are more stringent checks during the manufacturing process and clinical trials are required to demonstrate similar efficacy and pharmacokinetic properties.

In clinical trials of biosimilars, more attention is paid to immunogenicity, development of antibodies to the new product, adverse reactions and safety.

One important issue to note about biologics is that production methods change with time and there have often been changes to production processes of the originator products during their period of exclusivity. This has resulted in products that might be different from when they were first licensed, although their principal biological mechanism of action remains the same. This is known as 'iterative'

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change and each such change in manufacturing is agreed with regulatory authorities before it is implemented.

What biosimilars are already in use and what others are coming soon?

A number of biosimilars have already appeared on the market, notably growth hormone (somatotropin), haematologicals such as granulocyte stimulating factors and erythropoietin, as well as a diverse range of monoclonal antibodies to treat inflammatory and malignant diseases. Two biosimilars for infliximab were marketed earlier this year, now biosimilar insulin glargine (Abasaglar®) has been launched. Biosimilar etanercept is likely to be available soon, it is currently being assessed by the EMA.

How will biosimilar insulin glargine (Abasaglar®) be introduced?

Clinicians, pharmacists, nursing staff and patients will all need to be aware that biosimilar insulin glargine is available. It is clearly important to be able to identify the particular biologic product an individual patient is using and the MHRA has said that there should not be automatic substitution of biosimilar for the original or reference product.[1] Prescribing by brand name is therefore essential to ensure continuity of treatment for patients. This will also enable appropriate reporting of safety issues, whether it involves the originator product or a biosimilar.

Changes in prescribing and dispensing

Prescribing and supply of insulin glargine

Prescriptions – will need to specify the brand intended. Generic prescriptions for insulin glargine should not be issued. Abasaglar® Is marketed in the Lilly Kwikpen, also as 3ml cartridges.
Dispensing: Pharmacies need to ensure that the appropriate brand of insulin glargine is dispensed, there should be no substitution of one brand for the other.
Records: GP records and hospital notes should identify the brand of insulin glargine being used in that patient.
GP practices should ensure that their patient records identify those patients currently on insulin glargine as being on the Lantus® brand, before Abasaglar® becomes more widely used
Communications between GPs and hospital should provide brand details of product prescribed.
Formularies will need to identify where it is appropriate to use the new biosimilar.
Patient education: patients should be educated about non-interchangeability of the brand of insulin glargine they are currently using and provided with the correct information in their insulin passport.
Adverse reactions (whether suspected or established) should be documented on yellow card reports to the MHRA, as previously. Abasaglar® is a 'black triangle' drug so all ADRs should be reported on a Yellow card, either electronically or using a form from a BNF.

Commissioning perspectives

Biosimilar insulin glargine (Abasaglar®) is around 15% cheaper and cost savings could be made if the new biosimilar is used instead of Lantus®, but this would not be not appropriate for many patients. Initiating the biosimilar may be appropriate for new patients who have not had insulin glargine previously or for those whose treatment is being reviewed due to poor control.
The majority of existing patients who are stabilised on Lantus® will not need to change treatment and there are risks in trying to do this, for example the two agents may not exert identical effects in an individual patient and there is a risk of unexpected daytime and / or nocturnal hypoglycaemia. Switching of large numbers of patients from one product to the other is not appropriate for the same reason.

Other brands of biosimilar insulin glargine are expected to be marketed in 2016 and 2017.

References
1. MHRA. Biosimilar products. Drug safety update 2008;vol 1:7:8, accessed via http://www.mhra.gov.uk/Safetyinformation/DrugSafetyUpdate/CON084739, accessed Sept 2015

Further reading: Chaplin S. Biosimilars: what are they and why do we need to know? Prescriber 2014: 25: 40-42

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