

Product Update

insulin glargine 100units/ml solution for injection in a vial, cartridge, pre-filled pen (Lantus®, Clikstar®, Lantus®Solostar®) (No: 860/13)

Sanofi

08 March 2013

The Scottish Medicines Consortium (SMC) has completed its assessment of the above product and advises NHS Boards and Area drug and Therapeutic Committees (ADTCs) on its use in NHS Scotland. The advice is summarised as follows:

ADVICE: following an abbreviated submission

insulin glargine is accepted for restricted use within NHS Scotland.

Indication under review: treatment of diabetes mellitus in adults, adolescents and children aged 2 years and above.

SMC restriction: patients in whom treatment with an insulin analogue is appropriate.

Its use should be targeted on patients with Type I diabetes who are at risk of or experience unacceptable frequency and/or severity of nocturnal hypoglycaemia on attempting to achieve better hypoglycaemic control during treatment with established insulins. It is also acceptable as a once daily insulin therapy for patients who require carer administration of their insulin.

In patients with type 2 diabetes it should be restricted to those who suffer from recurrent episodes of hypoglycemia or require assistance with their insulin injections.

The pre-filled pen has previously been accepted for restricted use in patients from the age of 6 years and above.

Advice context:

No part of this advice may be used without the whole of the advice being quoted in full.

This advice represents the view of the Scottish Medicines Consortium and was arrived at after evaluation of the evidence submitted by the company. It is provided to inform the considerations of Area Drug & Therapeutics Committees and NHS Boards in Scotland in determining medicines for local use or local formulary inclusion. This advice does not override the individual responsibility of health professionals to make decisions in the exercise of their clinical judgement in the circumstances of the individual patient, in consultation with the patient and/or guardian or carer.

This assessment is based on data submitted by the applicant company up to and including 15 February 2013. .

**Chairman
Scottish Medicines Consortium**