insulin glulisine solution for subcutaneous injection 100 units/ml (Apidra®) (No: 512/08)

Sanofi-aventis

Product Update

10 October 2008

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 glulisine (Apidra®) is accepted for restricted use within NHS Scotland for the treatment of adolescents and children, 6 years or older with diabetes mellitus, where treatment with insulin is required and for whom the use of a short-acting insulin analogue is appropriate.

Insulin glulisine has a similar efficacy to other short-acting insulins in reducing glycated haemoglobin and a similar pharmacokinetic profile to at least one other insulin analogue. It is restricted to use in patients where soluble human insulin is inappropriate.

The Scottish Medicines Consortium has previously accepted this product for restricted use for this indication in adults.

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 12 August 2008.

Chairman, Scottish Medicines Consortium

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