Scottish Medicines Consortium
Providing advice about the status of all newly licensed medicines
www.scottishmedicines.org.uk
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NHS SCOTLAND

somatropin 5.83mg/ml and 8mg/ml solution for injection (Saizen®) (No:737/11)

Merck Serono Ltd

07 October 2011

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

somatropin solution for injection (Saizen®) is accepted for use in NHS Scotland.

Indication under review:
Children and adolescents:
- Growth failure in children caused by decreased or absent secretion of endogenous growth hormone.
- Growth failure in girls with gonadal dysgenesis (Turner Syndrome), confirmed by chromosomal analysis.
- Growth failure in prepubertal children due to chronic renal failure (CRF).
- Growth disturbance (current height SDS <-2.5 and parental adjusted height SDS <-1) in short children born small for gestational age (SGA) with a birth weight and/or length below -2 SD, who failed to show catch-up growth (HV SDS <0 during the last year) by 4 years of age or later.

Adults:
- Replacement therapy in adults with pronounced growth hormone deficiency as diagnosed by a single dynamic test for growth hormone deficiency. Patients must also fulfil the following criteria:

- Childhood Onset:
Patients who were diagnosed as growth hormone deficient during childhood, must be retested and their growth hormone deficiency confirmed before replacement therapy with Saizen is started.

- Adult Onset:
Patients must have growth hormone deficiency as a result of hypothalamic or pituitary disease and at least one other hormone deficiency diagnosed (except for prolactin) and adequate replacement therapy instituted, before replacement therapy using growth hormone may begin.

This new formulation has been shown to be bioequivalent to the previously available freeze-dried formulation and is available at an equivalent cost. It is in a ready to use cartridge and does not require reconstitution.

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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 16 August 2011.

Chairman
Scottish Medicines Consortium