

Product Update:

recombinant E.coli asparaginase 10,000 units powder for concentrate for solution for infusion (Spectrila®) SMC No 1319/18
medac Pharma LLP

9 March 2018

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

asparaginase (Spectrila®) is accepted for use within NHS Scotland.

Indication under review: as a component of antineoplastic combination therapy for the treatment of acute lymphoblastic leukaemia (ALL) in paediatric patients from birth to 18 years and adults.

Asparaginase produced in E. coli cells has been used in NHS Scotland as an unlicensed medicine as part of treatment of ALL in children and adults; asparaginase (Spectrila®) provides a licensed alternative.

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 13 December 2017.

Chairman
Scottish Medicines Consortium