

Product Update:

entecavir, 0.5 and 1mg film-coated tablets and 0.05mg/mL oral solution
(Baraclude[®]) SMC No. (1049/15)

Bristol-Myers Squibb Pharmaceuticals Ltd

10 April 2015

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

entecavir (Baraclude[®]) is accepted for restricted use within NHS Scotland.

Indication under review: treatment of chronic hepatitis B virus infection in nucleoside naive paediatric patients from 2 to <18 years of age with compensated liver disease who have evidence of active viral replication and persistently elevated serum alanine aminotransferase levels, or histological evidence of moderate to severe inflammation and/or fibrosis.

SMC restriction: to be prescribed under the supervision of specialists in paediatric infectious diseases.

While the benefits of viral suppression in adults are acknowledged the benefits of anti-viral treatment in children are less well established. In clinical studies, the antiviral efficacy of entecavir in children is reported to be lower than in adults. However there is a potential need for treatment in a very small number of paediatric patients and this is the first licensed medicine for hepatitis B in this age group.

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 February 2015.

Chairman
Scottish Medicines Consortium

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