Scottish Medicines Consortium



Ibuprofen intravenous injection 5mg/ml (Pedea^ò) Orphan Europe (UK) Ltd

(No. 233/06)

New Product

6 January 2006

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

Ibuprofen intravenous injection 5mg/ml (Pedea) is accepted for use within NHSScotland for the treatment of haemodynamically significant patent ductus arteriosus in pre-term newborn infants of less than 34 weeks gestational age. Safety and efficacy compared to existing alternative treatments has not been formally assessed.

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 November 2005.

Chairman Scottish Medicines Consortium