

Product Update

alteplase 2mg powder and solvent for solution for injection for infusion (Actilyse Cathflo®) (No: 717/11)

Boehringer Ingelheim

08 July 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

alteplase 2mg powder and solvent for solution for injection (Actilyse Cathflo®) is accepted for restricted use within NHS Scotland.

Indication under review: thrombolytic treatment of occluded central venous access devices including those used for haemodialysis.

SMC restriction: to use where alteplase is the product of choice for the treatment of occluded venous access devices.

This is a new formulation introduced for this extension to the alteplase marketing authorisation and the 2 ml vial is the only presentation licensed for this indication.

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 17 June 2011.

**Chairman
Scottish Medicines Consortium**

Published 08 August 2011