

valganciclovir powder for 50mg/ml oral solution (Valcyte®) (No: 587/09)

Roche

Product Update

06 November 2009

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

valganciclovir powder for 50mg/ml oral solution (Valcyte®) is accepted for restricted use in NHS Scotland for the prevention of CMV disease in CMV-negative patients who have received a solid organ transplant from a CMV-positive donor.

Valganciclovir should only be initiated by physicians experienced in the care of post-transplant patients. In patients for whom valganciclovir is an appropriate choice of therapy this is the only licensed formulation for those undergoing haemodialysis (creatinine clearance <10ml/minute). Otherwise its use should be restricted to patients unable to use the less costly solid oral dosage form.

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 September 2009.

Chairman Scottish Medicines Consortium