

tipranavir (Aptivus) 250mg soft capsule (No: 616/10)
Boehringer Ingelheim International

Product Update

15 January 2010

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

tipranavir 250mg soft capsules (Aptivus®) in combination with low dose ritonavir are accepted for restricted use within NHS Scotland for combination antiretroviral treatment of HIV-1 infection in highly pre-treated adolescents 12 years of age or older with virus resistant to multiple protease inhibitors.

The marketing authorisation for tipranavir states that it should only be used as part of an active combination antiretroviral regimen in patients with no other therapeutic options. In adult patients the Scottish Medicines Consortium has restricted tipranavir to patients with a tipranavir mutation score of less than 4 and this restriction should also apply to this licence extension covering adolescents 12 years of age and older. Tipranavir is listed in the British National Formulary for Children for the treatment of HIV infection.

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 **11 November 2009***

Chairman
Scottish Medicines Consortium