



**Final Appraisal Recommendation**  
Advice No: 4015 – December 2015

**Efavirenz (Sustiva®) 50 mg, 100 mg, 200 mg hard capsules and  
600 mg film-coated tablets**

**Limited submission by Bristol-Myers Squibb  
Pharmaceuticals Ltd**

**Recommendation of AWMSG**

**Efavirenz (Sustiva®) is recommended as an option for use within NHS Wales in antiviral combination treatment for the treatment of human immunodeficiency virus-1 (HIV-1) infected children 3 months of age to 3 years and weighing at least 3.5 kg.**

**Sustiva® has not been adequately studied in patients with advanced HIV disease, namely patients with CD4 counts < 50 cells/mm<sup>3</sup>, or after failure of protease inhibitor (PI) containing regimens. Although cross-resistance of efavirenz with PIs has not been documented, there are at present insufficient data on the efficacy of subsequent use of PI based combination therapy after failure of regimens containing Sustiva®.**

**Additional note(s):**

- Please refer to the Summary of Product Characteristics for the full licensed indication.

In reaching the above recommendation AWMSG has taken account of the appraisal documentation prepared by the AWMSG Secretariat (reference number 2666), which includes the AWMSG Secretariat Assessment Report (ASAR), the Preliminary Appraisal Recommendation (PAR) and the applicant company's response to the PAR, clinical expert opinion (where available), the views of patients/patient carers (where available) and the lay member perspective.

This recommendation has been ratified by Welsh Government and will be considered for review every three years.

Marketing authorisation holder on first issue	Bristol-Myers Squibb Pharmaceuticals Ltd
Date of first issue	December 2015
Last reviewed	March 2019



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