



### Final Appraisal Recommendation

Advice No: 2913 – October 2013

## Raltegravir (Isentress<sup>®</sup>) 25 mg and 100 mg chewable tablets and 400 mg film-coated tablets

Limited submission by Merck Sharp & Dohme Ltd

### Recommendation of AWMSG

Raltegravir (Isentress<sup>®</sup>) 25 mg and 100 mg chewable tablets, in combination with other anti-retroviral medicinal products for the treatment of human immunodeficiency virus (HIV-1) infection in children are recommended as an option for restricted use within NHS Wales.

Raltegravir (Isentress<sup>®</sup>) 400 mg film-coated tablets, in combination with other anti-retroviral medicinal products for the treatment of HIV-1 infection in adolescents and children from the age of 6 years and weighing  $\geq 25$  kg, are recommended as an option for restricted use within NHS Wales.

Raltegravir (Isentress<sup>®</sup>) 25 mg and 100 mg chewable tablets and 400 mg film-coated tablets should be restricted for use in patients who are resistant or intolerant to non-nucleoside reverse transcriptase inhibitors (NNRTIs) or protease inhibitors (PIs), or for whom these options are compromised due to drug–drug interactions.

#### Additional note:

- 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 1609), 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:	Merck Sharp & Dohme Ltd
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Last reviewed	December 2016



NICE has accredited the process used by the All Wales Medicines Strategy Group (AWMSG) to produce its final appraisal recommendation. Accreditation is valid for 5 years from October 2011. More information on accreditation can be viewed at [www.evidence.nhs.uk](http://www.evidence.nhs.uk).

For full details on our accreditation visit: [www.nice.org.uk/accreditation](http://www.nice.org.uk/accreditation).

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