All Wales Medicines Strategy Group

Grŵp Strategaeth Meddyginiaethau Cymru Gyfan

Final Appraisal Recommendation
Advice No: 2115 – July 2015

Darunavir/cobicistat (Rezolsta®▼) 800 mg/150 mg film-coated capsules

Submission by Janssen-Cilag Ltd

Recommendation of AWMSG

Darunavir/cobicistat (Rezolsta®▼) is recommended as an option for use within NHS Wales in combination with other antiretroviral medicinal products for the treatment of human immunodeficiency virus-1 (HIV-1) infection in adults aged 18 years or older.

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 2193), 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	Janssen-Cilag Ltd
Date of first issue	July 2015
Last reviewed	March 2019

NICE accredited
www.nice.org.uk/accreditation

NICE has accredited the process used by the All Wales Medicines Strategy Group (AWMSG) to produce its final appraisal recommendations. Accreditation is valid for 5 years from October 2016. More information on accreditation can be viewed at http://www.nice.org.uk/about/what-we-do/accreditation