



Final Appraisal Recommendation

Advice No: 1815 – June 2015

Darunavir (Prezista®) film-coated tablets and 100 mg/ml oral suspension

Limited submission by Janssen-Cilag Ltd

Recommendation of AWMSG

Darunavir (Prezista®) co-administered with low dose ritonavir in combination with other antiretroviral medicinal products is recommended as an option for use within NHS Wales for the treatment of human immunodeficiency virus (HIV-1) infection in paediatric patients from the age of three years and at least 15 kg body weight.

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 2579), 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	June 2015
Last reviewed	April 2019

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All Wales Medicines Strategy Group. Final Appraisal Recommendation – 1815:
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