Scottish Medicines Consortium
Providing advice about the status of all newly licensed medicines
www.scottishmedicines.org.uk
Delta House 50 West Nile Street Glasgow G1 2NP Tel 0141 225 6999 Chairman: Professor Angela Timoney FRPharmS
NHS SCOTLAND

Product Update:

darunavir 400mg, 800mg film-coated tablets and oral suspension 100mg/mL (Prezista®) (No: 948/14)

Janssen-Cilag Ltd

07 February 2014

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

darunavir (Prezista®) is accepted for restricted use within NHS Scotland.

Indication under review: darunavir co-administered with low dose ritonavir in combination with other antiretroviral medicinal products for the treatment of human immunodeficiency virus (HIV-1) infection in paediatric patients 12 to 17 years of age and at least 40kg body weight who are: antiretroviral therapy (ART) naïve; or, ART-experienced with no darunavir resistance associated mutations and who have plasma HIV-1 RNA <100,000 copies/mL and CD4+ cell count ≥100 cells/mm^3.

SMC restriction: in patients <18 years, to be prescribed under the supervision of specialists in paediatric HIV.

The Scottish Medicines Consortium has previously accepted darunavir for use in this indication in adults and in highly pre-treated children and adolescents, from the age of 6 years and at least 20kg body weight, who have failed on more than one regimen containing a protease inhibitor. Darunavir is listed in the British National Formulary for Children in combination with other antiretroviral drugs, for HIV infection resistant to other protease inhibitors in children previously treated with antiretrovirals.

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 05 December 2014

Chairman
Scottish Medicines Consortium

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