

Product Update

darunavir oral suspension 100mg/mL (Prezista®) (No: 861/13)

Janssen-Cilag Ltd

08 March 2013

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

Indication under review: co-administered with low dose ritonavir in combination with other antiretroviral medicinal products for the treatment of human immunodeficiency virus (HIV-1) infection in adult patients as well as antiretroviral therapy (ART)-experienced paediatric patients from the age of 3 years and at least 15 kg body weight.

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

Darunavir is listed in the British National Formulary for Children for the treatment of HIV resistant to other protease inhibitors. 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.

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 5 February 2013.

Chairman, Scottish Medicines Consortium

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