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 Jonathan G Fox

Product Update:

raltegravir granules for oral suspension 100mg (Isentress®)

SMC No. (1102/15)

Merck Sharp & Dohme Limited

9 October 2015

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 Scotland. The advice is summarised as follows:

ADVICE: following an abbreviated submission

raltegravir granules for oral suspension (Isentress®) are accepted for restricted use within NHS Scotland.

Indication under review: in combination with other anti-retroviral medicinal products for the treatment of human immunodeficiency virus (HIV-1) infection in adults, adolescents, children, toddlers and infants from the age of 4 weeks.

SMC restriction: patients who are intolerant or resistant to non-nucleoside reverse transcriptase inhibitors (NNRTIs) or protease inhibitors (PIs) or when these options are compromised due to drug-drug interactions; raltegravir granules should be prescribed under the supervision of specialists in paediatric HIV.

The granules for oral suspension are licensed for use in patients weighing 3kg to 20kg and provide an alternative formulation for infants where chewable tablets are not suitable.

Because the formulations are not bioequivalent, neither the granules for oral suspension nor the chewable tablets should be substituted for the 400 mg film-coated tablet.

SMC has previously accepted raltegravir 25mg and 100mg chewable tablets and raltegravir 400mg film-coated tablets for restricted use in combination with other anti-retroviral medicinal products for the treatment of HIV-1 infection in adolescents and children aged 2 to 17 years and in adult patients. Raltegravir is listed in the British National Formulary for Children for the treatment of HIV infection.

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 07 August 2015.

Chairman
Scottish Medicines Consortium